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# Original Research

## Diagnostic Accuracy of Combined Ultrasonography and Colour Doppler in Differentiation of Benign and Malignant Gynaecological Pelvic Masses: A Prospective Study

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#### ABSTRACT:

Background: Early differentiation between benign and malignant pelvic masses is crucial for appropriate management. This study aimed to evaluate the diagnostic accuracy of combined grey-scale ultrasonography and colour Doppler in characterizing gynaecological pelvic masses. Methods: This prospective, observational study included 156 consecutive patients with clinically suspected pelvic masses referred to the Gynaecology Department between January 2023 and December 2023. All patients underwent transvaginal and/or transabdominal ultrasonography with colour Doppler assessment before surgical intervention. Ultrasonographic features (morphology, size, wall characteristics, solid components) and Doppler parameters (vascular location, resistive index, pulsatility index) were recorded and compared with histopathological diagnosis as the gold standard. Results: Of 156 patients, histopathology confirmed 124 (79.5%) benign and 32 (20.5%) malignant lesions. Combined grey-scale and Doppler evaluation achieved sensitivity, specificity, positive predictive value, and negative predictive value of 93.8%, 91.1%, 73.2%, and 98.3%, respectively. Significant predictors of malignancy included complex echogenicity (OR 5.8, 95% CI 2.4-14.2), thick irregular septations (OR 7.3, 95% CI 3.1-17.2), presence of solid components (OR 8.9, 95% CI 3.6-22.4), central or septal vascularity (OR 6.7, 95% CI 2.9-15.6), and resistive index <0.4 (OR 11.2, 95% CI 4.3-29.1). Conclusions: Combined grey-scale ultrasonography and colour Doppler provides high diagnostic accuracy in differentiating benign from malignant pelvic masses. Integration of morphological and vascular assessment significantly improves diagnostic performance compared to either modality alone and should be incorporated into routine clinical practice.

Keywords: Gynaecological pelvic mass, ultrasonography, colour Doppler, malignancy, diagnostic accuracy

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#### INTRODUCTION

Gynaecological pelvic masses represent a common clinical challenge with significant diagnostic and therapeutic implications. The spectrum of pathologies ranges from functional and benign lesions to invasive malignancies, necessitating accurate preoperative characterization to guide management decisions and optimize patient outcomes.<sup>1</sup> Ovarian cancer, in particular, remains the leading cause of gynaecological cancer-related mortality, with fiveyear survival rates heavily dependent on stage at diagnosis.<sup>2</sup>

Traditional grey-scale ultrasonography has been the primary imaging modality for initial evaluation of pelvic masses due to its wide availability, costeffectiveness, and absence of ionizing radiation.<sup>3</sup> However, its specificity in differentiating benign from malignant lesions remains suboptimal, with reported values ranging from 62% to 83%.<sup>4</sup> The introduction of colour Doppler technology has provided additional vascular information that complements morphological assessment, potentially enhancing diagnostic accuracy.<sup>5</sup>

The pathophysiological basis for Doppler assessment lies in the abnormal neovascularization associated with malignancy. Tumour angiogenesis results in vessels lacking normal muscular elements, leading to decreased vascular resistance and altered flow patterns that can be quantified through spectral Doppler indices.<sup>6</sup> These characteristics potentially allow differentiation from the higher-resistance vasculature typically observed in benign lesions.

While previous studies have investigated various ultrasonographic and Doppler parameters individually, comprehensive evaluation of combined assessment in clinical practice has yielded variable results.<sup>7–9</sup> Differences in study populations, examination techniques, and diagnostic criteria have contributed to heterogeneity in reported performance metrics, highlighting the need for standardized approaches with prospective validation.

This study aimed to evaluate the diagnostic accuracy of combined grey-scale ultrasonography and colour Doppler in differentiating benign from malignant gynaecological pelvic masses, using histopathological diagnosis as the reference standard. Additionally, we sought to identify the most discriminative individual parameters and develop an optimized assessment protocol for clinical implementation.

### MATERIALS AND METHODS

#### **Study Design and Population**

This prospective, observational study was conducted at University Medical Center between January 2023 and December 2023. The study protocol was approved by the Institutional Ethics Committee (approval number UMC-2022-156), and written informed consent was obtained from all participants.

Consecutive female patients aged  $\geq 18$  years presenting with clinically suspected pelvic masses were recruited. **Inclusion criteria were:** (1) clinically palpable adnexal or pelvic mass; (2) ultrasonographically detected pelvic mass of probable gynaecological origin; and (3) planned surgical intervention with histopathological examination.

**Exclusion criteria included:** (1) previously diagnosed and treated pelvic malignancy; (2) pregnancy; (3) exclusively solid uterine masses consistent with fibroids; (4) inability to undergo complete ultrasonographic examination; and (5) refusal of surgical management.

Sample size was calculated based on an expected malignancy prevalence of 20%, desired sensitivity of 90%, specificity of 85%, precision of  $\pm$ 7%, and confidence level of 95%, resulting in a required sample of 154 patients.

#### Ultrasonographic Examination

All patients underwent standardized ultrasonographic examination using a Voluson E10 ultrasound system (GE Healthcare, Chicago, IL) equipped with 5-9 MHz transvaginal and 3-5 MHz transabdominal probes. Examinations were performed by three experienced sonographers (>5 years of gynaecological ultrasound experience) who were blinded to clinical information beyond the presence of a suspected pelvic mass.

Initial transabdominal scanning was performed with a moderately filled bladder to provide overview of the pelvis and assess large masses or extensive disease. This was followed by transvaginal ultrasonography after bladder emptying for detailed characterization of pelvic structures. For patients where transvaginal examination was not feasible (virginal status, severe vaginal stenosis), comprehensive transabdominal scanning was performed.

#### **Grey-scale Evaluation**

The following grey-scale parameters were systematically assessed and documented:

- 1. Size: Maximum diameter in three orthogonal planes
- 2. Location: Uterine, right adnexal, left adnexal, or indeterminate
- 3. Echogenicity: Anechoic, hypoechoic, hypoechoic, mixed, or complex
- 4. Cyst wall: Smooth/regular or irregular/nodular
- 5. Wall thickness: Thin (<3 mm) or thick ( $\geq 3 \text{ mm}$ )
- 6. Septations: Absent, thin (<3 mm), or thick ( $\geq$ 3 mm)
- 7. Solid components: Absent, present as mural nodules, or predominantly solid
- 8. Ascites: Present or absent
- 9. Ancillary findings: Peritoneal deposits, lymphadenopathy

#### **Colour Doppler Assessment**

Colour Doppler settings were optimized for detection of low-velocity flow with pulse repetition frequency of 0.3-0.9 kHz, wall filter of 30-50 Hz, and colour gain adjusted just below the noise threshold. Power Doppler was applied when conventional colour Doppler failed to detect vascularity.

Vascular parameters evaluated included:

- 1. Vascularity: Absent, minimal, moderate, or marked
- 2. Vessel location: Peripheral, central, or septal
- 3. Vascular pattern: Regular/orderly or irregular/chaotic

Spectral Doppler waveforms were obtained from at least three different vessels within the mass, with angle correction applied to maintain angles below  $60^{\circ}$ . The following indices were calculated:

- 1. Resistive Index (RI): (Peak systolic velocity -End diastolic velocity) / Peak systolic velocity
- 2. Pulsatility Index (PI): (Peak systolic velocity -End diastolic velocity) / Mean velocity
- 3. Peak Systolic Velocity (PSV) in cm/s

The lowest RI and PI values and highest PSV from any tumour vessel were recorded for analysis.

#### Surgical Management and Histopathology

All patients underwent surgical management based on clinical indication and preoperative assessment. Procedures included laparoscopy, laparotomy, or vaginal approaches as appropriate. Specimens were submitted for histopathological examination according to standard institutional protocols.

Pathologists were blinded to ultrasonographic findings. Histopathological diagnosis was established according to WHO classification criteria for female

genital tract tumours and served as the reference standard for analysis.

#### **Statistical Analysis**

Data analysis was performed using SPSS version 26.0 (IBM Corp., Armonk, NY). Continuous variables were expressed as mean  $\pm$  standard deviation or median (interquartile range) based on distribution normality assessed by Shapiro-Wilk test. Categorical variables were presented as frequencies and percentages.

Differences between benign and malignant groups were compared using Student's t-test or Mann-Whitney U test for continuous variables and chisquare or Fisher's exact test for categorical variables, as appropriate.

Diagnostic performance metrics including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy were calculated with 95% confidence intervals for individual parameters and combined assessment. Receiver operating characteristic (ROC) curves were constructed, and area under the curve (AUC) values were determined.

Multivariate logistic regression analysis identified independent predictors of malignancy. Variables with P<0.1 in univariate analysis were included in the multivariate model, with results expressed as odds ratios (OR) with 95% confidence intervals (CI).

Inter-observer agreement was assessed using Cohen's kappa coefficient for categorical variables and intraclass correlation coefficient for continuous measurements. P values <0.05 were considered statistically significant.

#### RESULTS

## Patient Demographics and Histopathological Findings

A total of 172 patients with suspected pelvic masses were initially evaluated. After excluding 16 patients (8 declined surgery, 5 had incomplete ultrasonographic examination, 3 had non-gynaecological masses), 156 patients were included in the final analysis.

The mean age of patients was  $48.3 \pm 16.7$  years (range 19-82 years). Presenting symptoms included abdominal pain (64.1%), abdominal distension (42.3%), abnormal vaginal bleeding (26.9%), and incidental finding on routine examination (17.9%).

Table 1. Histopathological Diagnosis of Pelvic Masses (n=156)

Diagnosis	Number	Percentage
Benign (n=124)		
Serous cystadenoma	32	20.5%
Mucinous cystadenoma	17	10.9%
Mature teratoma (dermoid cyst)	26	16.7%
Endometrioma	19	12.2%
Functional cyst	11	7.1%
Fibroma/thecoma	8	5.1%
Tubo-ovarian abscess	5	3.2%
Paraovarian cyst	4	2.6%
Leiomyoma	2	1.3%
Malignant (n=32)		
Serous cystadenocarcinoma	13	8.3%
Mucinous cystadenocarcinoma	6	3.8%
Endometrioid adenocarcinoma	5	3.2%
Clear cell carcinoma	3	1.9%
Borderline tumour	3	1.9%
Granulosa cell tumour	1	0.6%
Metastatic tumour	1	0.6%

#### Table 2. Grey-scale Ultrasonographic Characteristics of Benign and Malignant Pelvic Masses

Characteristic	Benign (n=124)	Malignant (n=32)	<b>P-value</b>
Echogenicity			< 0.001
Anechoic	28 (22.6%)	0 (0%)	
Hypoechoic	21 (16.9%)	2 (6.3%)	
Hyperechoic	17 (13.7%)	1 (3.1%)	
Mixed	46 (37.1%)	9 (28.1%)	
Complex	12 (9.7%)	20 (62.5%)	
Wall characteristics			< 0.001
Smooth/regular	109 (87.9%)	7 (21.9%)	
Irregular/nodular	15 (12.1%)	25 (78.1%)	
Wall thickness			< 0.001
Thin (<3 mm)	102 (82.3%)	8 (25.0%)	

Thick (≥3 mm)	22 (17.7%)	24 (75.0%)	
Septations			< 0.001
Absent	53 (42.7%)	6 (18.8%)	
Thin (<3 mm)	61 (49.2%)	7 (21.9%)	
Thick (≥3 mm)	10 (8.1%)	19 (59.4%)	
Solid components			< 0.001
Absent	85 (68.5%)	3 (9.4%)	
Mural nodules	32 (25.8%)	10 (31.3%)	
Predominantly solid	7 (5.6%)	19 (59.4%)	
Ascites	6 (4.8%)	18 (56.3%)	< 0.001
Peritoneal deposits	0 (0%)	7 (21.9%)	< 0.001
Lymphadenopathy	2 (1.6%)	9 (28.1%)	< 0.001

Table 3. Colour Doppler Characteristics of Benign and Malignant Pelvic Masses

Characteristic	Benign (n=124)	Malignant (n=32)	<b>P-value</b>
Vascularity			< 0.001
Absent	31 (25.0%)	0 (0%)	
Minimal	54 (43.5%)	3 (9.4%)	
Moderate	32 (25.8%)	12 (37.5%)	
Marked	7 (5.6%)	17 (53.1%)	
Vessel location			< 0.001
Peripheral	87 (70.2%)	5 (15.6%)	
Central	4 (3.2%)	13 (40.6%)	
Septal	2 (1.6%)	14 (43.8%)	
Not applicable (no flow)	31 (25.0%)	0 (0%)	
Vascular pattern			< 0.001
Regular/orderly	89 (71.8%)	8 (25.0%)	
Irregular/chaotic	4 (3.2%)	24 (75.0%)	
Not applicable (no flow)	31 (25.0%)	0 (0%)	
Resistive Index (RI)	$0.68\pm0.13$	$0.38\pm0.09$	< 0.001
Pulsatility Index (PI)	$1.42\pm0.47$	$0.72\pm0.29$	< 0.001
Peak Systolic Velocity (PSV)	$11.6 \pm 6.4$	$24.7\pm10.2$	< 0.001

Spectral Doppler analysis revealed significantly lower RI and PI values and higher PSV in malignant masses compared to benign lesions (all P<0.001). ROC analysis identified optimal cutoff values of  $\leq 0.42$  for RI (sensitivity 87.5%, specificity 89.5%),  $\leq 0.85$  for PI (sensitivity 84.4%, specificity 83.9%), and  $\geq 18$  cm/s for PSV (sensitivity 78.1%, specificity 83.1%).

Univariate analysis demonstrated that marked vascularity (OR 19.2, 95% CI 7.0-52.4), central or

septal vessel location (OR 32.8, 95% CI 12.3-87.6), irregular vascular pattern (OR 86.0, 95% CI 25.2-293.5), RI  $\leq$ 0.42 (OR 58.2, 95% CI 19.1-177.6), PI  $\leq$ 0.85 (OR 28.4, 95% CI 10.1-79.9), and PSV  $\geq$ 18 cm/s (OR 17.9, 95% CI 7.0-45.8) were significant predictors of malignancy.

ROC analysis for Doppler parameters alone showed an AUC of 0.918 (95% CI 0.864-0.972) for differentiating benign from malignant masses.

Table 4. Multivariate Analysis of Independent Predictors for Malignancy

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Parameter	Adjusted OR	95% CI	<b>P-value</b>	
Complex echogenicity	5.8	2.4-14.2	< 0.001	
Thick irregular septations	7.3	3.1-17.2	< 0.001	
Solid components	8.9	3.6-22.4	< 0.001	
Central or septal vascularity	6.7	2.9-15.6	< 0.001	
Resistive index ≤0.42	11.2	4.3-29.1	< 0.001	

Assessment	Sensitivity	Specificity	PPV	NPV	Accuracy
	(95% CI)	(95% CI)	(95% CI)	(95% CI)	(95% CI)
Grey-scale alone	87.5% (71.9-	83.1% (75.6-	56.0% (42.3-	96.2% (90.7-	84.0% (77.4-
	95.0)	88.6)	68.8)	98.5)	88.9)
Doppler alone	90.6% (75.8-	87.9% (81.0-	64.4% (49.8-	98.3) 97.3% (92.3-	88.5% (82.5-
TT CONTRACTOR	96.8)	92.5)	76.8)	99.1)	92.6)

Combined	93.8% (79.9-	91.1% (84.7-	73.2% (57.8-	98.3% (93.9-	91.7% (86.2-
assessment	98.3)	95.0)	84.6)	99.5)	95.2)

#### DISCUSSION

This prospective study demonstrates that combined grey-scale ultrasonography and colour Doppler evaluation provides high diagnostic accuracy in differentiating benign from malignant gynaecological pelvic masses. The integration of morphological and vascular assessment significantly improved diagnostic performance compared to either modality alone, achieving sensitivity of 93.8%, specificity of 91.1%, and overall accuracy of 91.7%.

The multivariate analysis identified five independent predictors of malignancy: complex echogenicity, thick irregular septations, solid components, central or septal vascularity, and resistive index  $\leq 0.42$ . These findings align with the fundamental pathophysiological characteristics of malignant lesions, including architectural complexity and abnormal neovascularization with reduced vascular resistance.<sup>10</sup>

Grey-scale ultrasonography alone demonstrated good but suboptimal diagnostic performance with sensitivity of 87.5% and specificity of 83.1%. This moderate specificity reflects the overlap in morphological features between certain benign entities and malignancies.11 For instance, endometriomas with hemorrhagic components or mature teratomas with diverse tissue elements can present complex echogenicity patterns that mimic malignant lesions. Similarly, inflammatory processes such as tubo-ovarian abscesses may exhibit thick, irregular walls resembling malignant architectural distortion.

Our findings regarding grey-scale parameters are consistent with previous studies by Timmerman et al.,<sup>12</sup> who reported that morphological features including irregular solid components, wall irregularity, and septation characteristics were significant predictors of malignancy. Similarly, Valentin et al.<sup>13</sup> demonstrated in the IOTA (International Ovarian Tumor Analysis) studies that solid components and irregular internal architecture were strongly associated with malignancy risk.

Colour Doppler assessment alone showed improved performance with sensitivity of 90.6% and specificity of 87.9%. Vascular parameters, particularly spectral indices, demonstrated excellent discriminatory capacity. The optimal cutoff value of RI  $\leq$ 0.42 in our study aligns closely with thresholds reported in the literature, ranging from 0.4 to 0.45.<sup>14-16</sup> The pathophysiological basis for these findings lies in tumour angiogenesis, where rapid growth necessitates formation of new vessels lacking normal muscular elements, resulting in decreased resistance to blood flow.<sup>17</sup>

A notable finding was the importance of vessel location, with central and septal vascularity strongly associated with malignancy (adjusted OR 6.7). This

contrasts with peripheral vascularity typically seen in benign lesions, where vessels are displaced around the lesion rather than penetrating into it. Alcazar et al.<sup>18</sup> similarly reported that central vascularity demonstrated significantly higher association with malignancy compared to peripheral flow patterns.

The combined assessment using both grey-scale and Doppler parameters achieved the highest diagnostic accuracy, with AUC of 0.967. This synergistic effect reflects the complementary nature of morphological and vascular evaluation in characterizing pelvic masses. Integration of these modalities provides a more comprehensive assessment than either approach alone, particularly in challenging cases with overlapping features.

Our results support the findings of Testa et al.,<sup>19</sup> who demonstrated that combined assessment yielded higher diagnostic accuracy (AUC 0.94) compared to morphology alone (AUC 0.89) or Doppler alone (AUC 0.82). Similarly, Guerriero et al.<sup>20</sup> reported that adding colour Doppler to grey-scale evaluation increased specificity from 76% to 89% while maintaining high sensitivity.

The high negative predictive value (98.3%) of combined assessment is particularly clinically relevant, as it allows confident exclusion of malignancy in cases with reassuring ultrasonographic and Doppler features. This has important implications for management decisions, potentially reducing unnecessary surgical interventions for benign lesions suitable for conservative follow-up.

Several standardized assessment models have been developed to optimize diagnostic performance, including the Risk of Malignancy Index (RMI)<sup>21</sup> and the IOTA Simple Rules.<sup>22</sup> While these models have demonstrated good performance in external validation, they may not fully capture the diagnostic potential of integrating grey-scale and Doppler evaluation. Our findings suggest that systematic assessment of both morphological and vascular parameters should be incorporated into clinical practice, potentially in conjunction with established scoring systems.

Strengths of our study include its prospective design, standardized examination protocol, blinded assessment, and histopathological correlation in all cases. The inclusion of women across a wide age range with diverse pathologies enhances the generalizability of our findings to routine clinical practice.

Limitations include the single-center design and the moderate sample size, particularly for subgroup analyses of specific histopathological entities. Additionally, while our examiners were experienced sonographers, the operator-dependent nature of ultrasonography may limit generalizability to less experienced settings. Finally, the study did not formally compare performance with other assessment models such as the IOTA ADNEX model or incorporate serum biomarkers, which could potentially further enhance diagnostic accuracy.

#### CONCLUSION

Combined grey-scale ultrasonography and colour Doppler evaluation provides high diagnostic accuracy in differentiating benign from malignant gynaecological pelvic masses. Complex echogenicity, thick irregular septations, solid components, central or septal vascularity, and resistive index  $\leq 0.42$  are independent predictors of malignancy. Integration of morphological and vascular assessment significantly improves diagnostic performance compared to either modality alone and should be incorporated into routine clinical practice.

Future research should focus on external validation in diverse clinical settings, formal comparison with established risk prediction models, and the potential integration of novel ultrasonographic techniques such as three-dimensional assessment and contrastenhanced studies to further enhance diagnostic accuracy.

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