

Efficacy of Color Doppler Sonography And CA-125 for The Preoperative Diagnosis of Ovarian Cancer

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ABSTRACT

Background: Ovarian cancer remains the deadliest of the gynecological malignancies, with a 5-year overall survival rate of 35–49%. Because the disease typically produces few early symptoms and is often diagnosed only after it has advanced, early detection and accurate preoperative assessment of ovarian tumours remains challenging. **Objectives:** This study aimed to evaluate the efficacy of colour Doppler sonography and serum CA-125 in the preoperative diagnosis of ovarian cancer. **Methods & Materials:** This cross-sectional study included 35 patients diagnosed with ovarian tumours who were admitted for operative treatment at the Department of Obstetrics and Gynaecology and Gynaecologic Oncology of Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, from January to December 2015. **Results:** The mean age of the participants was 45.1 ± 12.9 years. Lower abdominal pain was the most common presenting symptom (45.7%). The majority of tumours (42.9%) measured 5.1–10.0 cm. Histopathology revealed 19 (54.3%) benign and 16 (45.7%) malignant tumours. The novel index showed the highest sensitivity (75.0%), accuracy (80.0%), positive predictive value (80.0%), and negative predictive value (80.0%) among the individual parameters. RI demonstrated the highest specificity (89.5%). Serum CA-125 showed 68.8% sensitivity, 84.2% specificity, and 77.1% accuracy. On ROC analysis, NI showed a high AUC of 0.933, followed by CA-125 (AUC 0.911), RI (0.775), and PI (0.699). **Conclusion:** The novel index demonstrated favourable diagnostic performance and may provide useful additional information for the preoperative differentiation of benign and malignant ovarian tumours. Colour Doppler indices and serum CA-125 may serve as

complementary tools in preoperative assessment.

Keywords: Ovarian Cancer, CA-125, Benign, Malignant, Color Doppler Sonography (CDS)

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INTRODUCTION

Ovarian cancer remains the deadliest of the gynecological malignancies, with a 5-year overall survival rate of 35–49% that falls to approximately 24% at 10 years. Survival is closely tied to stage at diagnosis: when the disease is detected early (stage I or II), surgery and chemotherapy cure 70–90% of patients, whereas diagnosis at a later stage (stage III or IV) yields a cure rate of 20% or less.^[1,2] This poor prognosis largely reflects the absence of early symptoms and the lack of an effective strategy for screening asymptomatic populations; screening itself carries considerable risk of false positives, including unnecessary major surgery in women who do not have cancer.^[3] Approximately 80% of ovarian tumours are benign, while the remaining 20% are malignant and carry a poor prognosis, with an overall five-year survival rate of only 19% at advanced stages.^[4] Because the disease typically produces few early

symptoms and is often diagnosed only after it has advanced, early detection and accurate preoperative assessment of ovarian tumours are essential goals in gynaecological practice. Patients diagnosed at an early stage have consistently better survival outcomes than those diagnosed later, underscoring the clinical value of distinguishing malignant from benign masses before surgery.^[5] Despite the need for early detection, effective screening methods for ovarian cancer remain limited, and only about 20–25% of cases are diagnosed at an early stage. Serum cancer antigen 125 (CA-125), human epididymis protein 4 (HE4), and transvaginal ultrasonography (TUS) are among the commonly used tools for the evaluation of ovarian tumours. However, CA-125 alone is not sufficient for differentiating malignant from benign ovarian masses, as its level can also be elevated in benign conditions such as endometriosis.^[6,7] Similarly, large

prospective studies have shown that CA-125 and TUS, whether used alone or in combination, have limited sensitivity and specificity for the early detection of ovarian cancer, identifying only about 30–45% of ovarian cancers at an early stage.^[8–10] Because of these limitations, the preoperative assessment of ovarian tumours relies mainly on the recognition of sonographic morphological features along with assessment of tumour vascularity by Doppler sonography. Based on their morphology, ovarian tumours can be broadly classified into five groups: unilocular cysts, unilocular solid cysts, multilocular cysts, multilocular solid cysts, and solid tumours.^[11] Based on this approach, the International Ovarian Tumor Analysis (IOTA) group developed a logistic regression model for estimating the preoperative risk of malignancy and established a standardized method for

ultrasound examination with clearly defined sonographic parameters.^[12]

Colour Doppler sonography (CDS) adds important information to the morphological assessment by allowing evaluation of the vascularity of ovarian tumours. It is a non-invasive, rapid, and reproducible technique and has shown good sensitivity and specificity in differentiating benign from malignant ovarian masses. Salem et al. (1994) demonstrated that the resistance index (RI) and pulsatility index (PI), obtained using colour and pulsed Doppler sonography, could help differentiate benign from malignant ovarian tumours preoperatively.^[13] Similar findings were reported by Bourne et al. (1993), Kurjak et al. (1992), Weiner et al. (1992), and Fleischer et al. (1992), who found that transvaginal colour and pulsed Doppler sonography could provide useful information for distinguishing benign from malignant ovarian tumours.^[5,14-16]

The present study aimed to evaluate the efficacy of colour Doppler sonography and serum CA-125 in the preoperative diagnosis of ovarian cancer.

METHODS & MATERIALS

This was a cross-sectional study conducted at the Department of Obstetrics and Gynaecology and Gynaecologic Oncology of Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, in collaboration with the National Institute of Nuclear Medicine and Allied Sciences (NINMAS) and the Pathology and Biochemistry departments of BSMMU. The study was conducted from January 2015 to December 2015. The study population comprised 35 diagnosed cases of ovarian tumour who were admitted for operative treatment at the Department of Obstetrics and Gynaecology and Gynaecologic Oncology of BSMMU.

These were the eligibility criteria of the study respondents:

Inclusion criteria

1. Patients who were clinically and ultrasonographically diagnosed with an ovarian tumour.
2. Patients admitted for operative treatment.
3. Patients who provided informed consent.

Exclusion criteria

1. Patients with ovarian tumour associated with uterine fibroid, pelvic inflammatory disease (PID), or endometriosis.
2. Patients with ovarian tumour associated with pregnancy.
3. Patients with ovarian tumour and severe ascites.
4. Patients aged less than 11 years.

Study Procedure: The study was cross-sectional and included 35 patients with diagnosed ovarian tumours admitted for operative treatment at BSMMU. Purposive sampling was used. After obtaining consent, history and clinical examination were performed. Transabdominal colour Doppler sonography was subsequently performed at NINMAS to assess the relevant vessels, and the pulsatility index (PI) and resistance index (RI) were calculated using the preset formulas. Serum CA-125 was measured from 3 mL of venous blood using the Microparticle Enzyme Immunoassay technique. Following surgery, the resected tumour tissue was sent to the Department of Pathology for histopathological examination, which was considered the reference standard. The findings of colour Doppler sonography and serum CA-125 were compared with the histopathological diagnosis. Sensitivity, specificity, accuracy, positive predictive value, and negative predictive value were calculated for differentiating benign from malignant ovarian tumours.

Data Collection and Analysis: After obtaining informed consent, data were collected from admitted patients with ovarian tumours, including clinical history, per-abdominal and pelvic examination, transabdominal sonography (TAS), colour Doppler sonography, serum CA-125 levels, RI, PI, novel index, and postoperative histopathological findings. Data were analysed using SPSS version 20.0 for Windows (SPSS Inc., Chicago, Illinois, USA). Mean values were calculated for continuous variables, while categorical variables were presented as frequencies and percentages. The Chi-square test was used to analyse categorical variables. Sensitivity, specificity, accuracy, positive predictive value, and negative predictive value of serum CA-125, PI, RI, and the novel index were evaluated to differentiate benign from malignant ovarian tumours. A P-value <0.05 was considered statistically significant.

Ethical Consideration: The ethical approval for the study was obtained from the Institutional Review Board (IRB) of Bangabandhu Sheikh Mujib Medical University (BSMMU).

RESULT

Table 1 shows the highest proportions in the 41–50-year and 51–60-year age groups (10 participants each, 28.6%). The mean age of the participants was 45.1 ± 12.9 years. The mean BMI was 19.4 ± 1.1 kg/m². Regarding presenting symptoms, lower abdominal pain was the most common symptom, reported by 16 participants (45.7%), followed by lower abdominal lump in 13 participants (37.1%) and lower abdominal heaviness in 7 participants (20.0%). Among the participants, 14 (40.0%) reported combined oral contraceptive use, whereas 21 (60.0%) reported non-use. Fertility-inducing drug use was reported by 4 participants (11.4%). A family history of BOC was reported by 13 participants (37.1%).

Table IDemographic and clinical characteristics of the study participants with ovarian tumour ($n=35$).

Variables	Number of Subjects	Percentage (%)
Age Distribution		
11–20 years	1	2.9%
21–30 years	6	17.1%
31–40 years	5	14.3%
41–50 years	10	28.6%
51–60 years	10	28.6%
61–70 years	3	8.6%
Mean $\pm$ SD (years)	45.1 $\pm$ 12.9	
BMI (kg/m ²)	19.4 $\pm$ 1.1	
Symptoms		
Lower abdominal pain	16	45.7%
Lower abdominal lump	13	37.1%
Lower abdominal heaviness	7	20.0%
Anorexia & weight loss	6	17.1%
Subfertility	1	2.9%
Oral Contraceptive Use		
Combined oral contraceptive use	14	40.0%
Combined oral contraceptive non-use	21	60.0%
Fertility Inducing Drugs	4	11.4%
Family History of BOC	13	37.1%

Table II presents that the majority of tumours (42.9%) measured 5.1–10.0 cm, followed by tumours measuring >10.0 cm (37.1%), while 7 (20.0%) tumours measured 3.1–5.0 cm. The majority of tumours were

unilateral (33, 94.3%). Regarding serum CA-125 levels, 21 participants (60.0%) had levels ≤ 35.0 U/mL, considered suggestive of a benign condition, while 14 (40.0%) had levels >35.0 U/mL, suggestive of

malignancy. Histopathological examination revealed that 19 (54.3%) of the tumours were benign, while 16 (45.7%) were malignant.

Table IIDistribution of study participants by tumour characteristics, serum CA-125 level, and histopathological diagnosis ($n=35$).

Variables	Number of Subjects	Percentage (%)
Tumor Size Distribution		
3.1–5.0 cm	7	20.0%
5.1–10.0 cm	15	42.9%
>10.0 cm	13	37.1%
Laterality of Tumor		
Unilateral	33	94.3%
Bilateral	2	5.7%
Serum CA-125 Level (U/mL)		
≤ 35.0 (suspected for benign)	21	60.0
>35.0 (suspected for malignancy)	14	40.0
Range (min–max)	5.9–5197	
Histopathological Diagnosis		
Benign	19	54.3%
Malignant	16	45.7%

Table III shows the distribution of tumour size and histopathological diagnosis according to the benign and malignant groups. Regarding tumour size, most benign tumours were in the 5.1–10.0 cm category (63.2%). In contrast, among malignant tumours, the majority measured >10.0 cm

(56.3%). A statistically significant association was observed between tumour size and histopathological diagnosis ($p=0.026$). Regarding histopathological diagnosis, among benign tumours, serous cystadenoma was the most common diagnosis (57.9%), followed by mucinous

cystadenoma (31.6%). Among malignant tumours, serous cystadenocarcinoma was the most frequent diagnosis (8, 50.0%), followed by borderline mucinous adenocarcinoma (25.0%), metastatic adenocarcinoma (18.8%), and immature cystic teratoma (6.3%).

Table IIIDistribution of ovarian tumours according to tumour size and histopathological diagnosis ($n = 35$).

Variables	Benign n (%)	Malignant n (%)	P-value
Tumour size (cm)			
3.1–5.0	3 (15.8)	4 (25.0)	0.026*
5.1–10.0	12 (63.2)	3 (18.8)	
>10.0	4 (21.1)	9 (56.3)	
Histopathological diagnosis			
Serous cystadenoma	11 (57.9)	–	
Mucinous cystadenoma	6 (31.6)	–	
Dermoid cyst	1 (5.3)	–	
Brenner tumour	1 (5.3)	–	
Serous cystadenocarcinoma	–	8 (50.0)	
Borderline mucinous adenocarcinoma	–	4 (25.0)	
Metastatic adenocarcinoma	–	3 (18.8)	
Immature cystic teratoma	–	1 (6.3)	

Note: *P value obtained using the chi-square test; * $p < 0.05$ (statistically significant).

Table IV presents the diagnostic classification of serum CA-125, PI, RI, NI, and the combined PI and NI in comparison with histopathological diagnosis as the reference standard. For CA-125, using a cut-off of ≥ 35 U/mL, 11 cases were correctly identified as positive and 16 as negative, with 3 false-positive and 5 false-negative

cases. For PI (<1.0), 9 cases were true positive and 16 were true negative, while 3 and 7 cases were false positive and false negative, respectively. For RI (<0.5), 7 cases were true positive and 17 were true negative. The novel index, using a cut-off of <1.5 , correctly identified 12 true-positive cases, with 16 true-negative, 3 false-

positive, and 4 false-negative cases. Thus, among the individual diagnostic indices, the novel index showed the highest number of true-positive classifications. When PI and NI were combined, 8 cases were true positive and 19 were false positive, while all 8 negative results were false negative.

Table IVComparison of diagnostic indices with histopathological diagnosis in ovarian tumours ($n = 35$).

Diagnostic index	Histopathological diagnosis	
	Positive (n=16)	Negative (n=19)
CA-125 level		
Positive (≥ 35 U/mL)	11 (True positive)	3 (False positive)
Negative (<35 U/mL)	5 (False negative)	16 (True negative)
Pulsatility index (PI)		
Positive (<1.0)	9 (True positive)	3 (False positive)
Negative (≥ 1.0)	7 (False negative)	16 (True negative)
Resistance index (RI)		
Positive (<0.5)	7 (True positive)	2 (False positive)
Negative (≥ 0.5)	9 (False negative)	17 (True negative)
Novel index (NI)		
Positive (<1.5)	12 (True positive)	3 (False positive)
Negative (≥ 1.5)	4 (False negative)	16 (True negative)
Combined Novel Index and Pulsatility Index		
Positive (PI <1 or NI <1.5) (n=27)	8 (True positive)	19 (False positive)
Negative (PI ≥ 1 or NI ≥ 1.5) (n=8)	8 (False negative)	0 (True negative)

In Table V, the novel index demonstrated the highest sensitivity (75.0%), accuracy (80.0%), positive predictive value (80.0%), and negative predictive value (80.0%) among the individual diagnostic parameters. RI showed the highest specificity (89.5%),

although its sensitivity was comparatively lower (43.8%). Serum CA-125 showed a sensitivity of 68.8%, specificity of 84.2%, and accuracy of 77.1%, while PI demonstrated a sensitivity of 56.3%, specificity of 84.2%, and accuracy of

71.4%. The combined PI and NI showed lower diagnostic validity, with a sensitivity of 50.0%, specificity of 0.0%, accuracy of 22.9%, positive predictive value of 29.6%, and negative predictive value of 0.0%.

Table VDiagnostic validity of serum CA-125, pulsatility index, resistance index, novel index, and combined novel index and pulsatility index for ovarian tumour ($n = 35$).

Validity test	Serum CA-125	Pulsatility index (PI)	Resistance index (RI)	Novel index (NI)	Combined PI and NI
Sensitivity (%)	68.8	56.3	43.8	75.0	50.0
Specificity (%)	84.2	84.2	89.5	84.2	0.0
Accuracy (%)	77.1	71.4	68.6	80.0	22.9
Positive predictive value (%)	78.6	75.0	77.8	80.0	29.6
Negative predictive value (%)	76.2	69.6	65.4	80.0	0.0

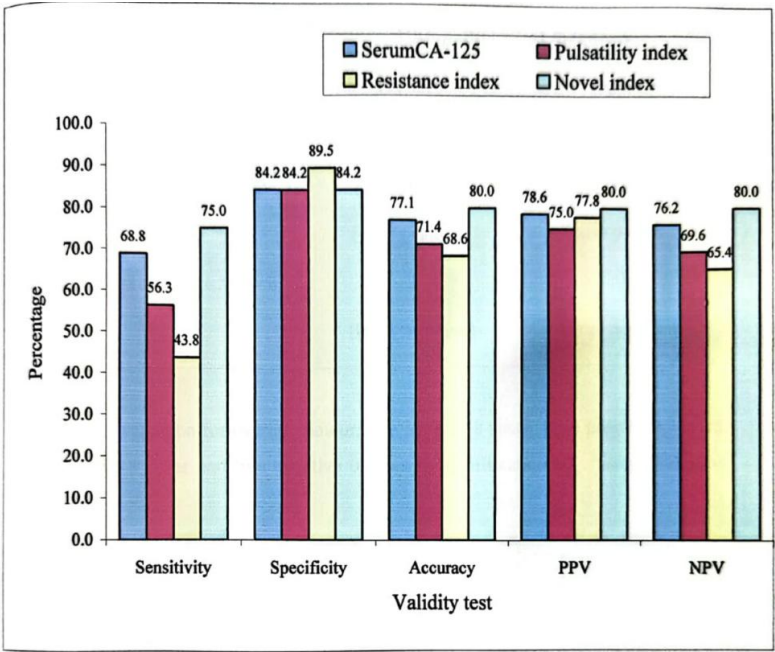


Figure 1: Bar diagram shows validity test of the study subjects.

The area under the receiver-operating characteristic (ROC) curves for the ovarian tumour predictors is presented in Table VI. ROC curves were constructed using the novel index, serum CA-125, pulsatility index (PI), and resistance index (RI) to assess their diagnostic performance in differentiating malignant from benign ovarian tumours. The novel index demonstrated a high discriminative ability, with an area under the ROC curve (AUC) of

0.933 (95% CI: 0.847–1.000). At the cut-off value of <1.5, the sensitivity and specificity of the novel index were 84.2% and 75.0%, respectively. For serum CA-125, a cut-off value of ≥ 35 U/mL yielded a sensitivity of 73.7% and specificity of 88.5%, with an AUC of 0.911 (95% CI: 0.799–0.982). The pulsatility index, at a cut-off of <1.0, showed a sensitivity of 68.4% and specificity of 62.5%, with an AUC of 0.699 (95% CI: 0.522–0.876). The resistance

index, at a cut-off of <0.5, demonstrated a sensitivity of 57.9% and specificity of 75.0%, with an AUC of 0.775 (95% CI: 0.616–0.933). Overall, the ROC analysis demonstrated good discriminative performance of the novel index (AUC 0.933), while PI showed the lowest AUC (0.699), indicating comparatively lower discriminatory ability.

Table VI

Receiver-operator characteristic (ROC) curve of serum CA-125, pulsatility index, resistance index and novel index for prediction of ovarian tumour.

	Cut-off value	Sensitivity	Specificity	Area under the ROC curve	95% CI Lower bound	95% CI Upper bound
Novel index	<1.5	84.2	75.0	0.933	0.847	1.000
CA-125	≥ 35	73.7	88.5	0.911	0.799	0.982
Pulsatility index (PI)	<1	68.4	62.5	0.699	0.522	0.876
Resistance index (RI)	<0.5	57.9	75.0	0.775	0.616	0.933

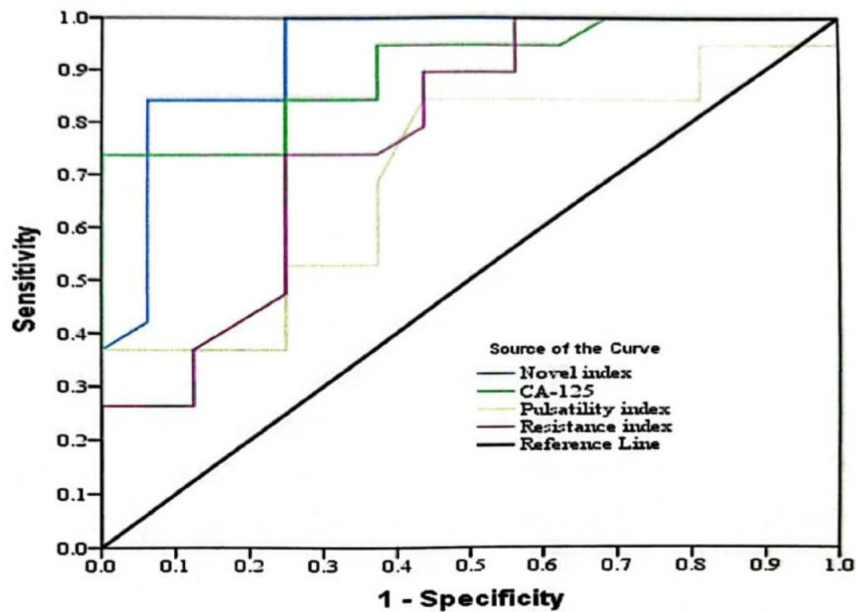


Figure 2 Receiver operating characteristic curves for serum CA-125, pulsatility index, resistance index, and novel index.

DISCUSSION

In the present study, ovarian tumours were most commonly observed among women in the fifth and sixth decades of life, with each group accounting for 28.6% of cases. The mean age was 45.1 ± 12.9 years, with an age range of 17–70 years. These findings are comparable with those of Hossain et al. (2010), who reported a mean age of 42.13 ± 17.6 years.^[17] In contrast, Alcazar et al. (2009) reported a higher mean age of 52.2 years, with a wider range of 15–84 years.^[18] Such differences may be related to variations in study populations and clinical settings.

The mean BMI in the present study was 19.4 ± 1.1 kg/m², ranging from 18–22 kg/m². This was lower than the mean BMI of 26 kg/m² reported by Backes et al. (2011), whose participants also showed a wider range of BMI values (16.4–49.1 kg/m²).^[19] Lower abdominal pain was the most common presenting symptom in the present study (45.7%), followed by lower abdominal lump (37.1%), abdominal heaviness (20.0%), anorexia and weight loss (17.1%), and subfertility (2.9%). Choudhury et al. (2005) reported abdominal lump as the main presenting complaint in 95% of cases.^[20]

A positive family history of breast or ovarian cancer was reported in 37.1% of cases in the present study, compared with 20.0% reported by Malik (2002).^[21] A family history of ovarian or breast cancer may indicate an inherited predisposition, including germline mutations involving BRCA1 or BRCA2 (Shen-Gunther and Mannel 2002; Rufford et al. 2007).^[22,23] Most tumours in the present study measured 5.1–10.0 cm (42.9%), followed by those >10 cm (37.1%) and 3.1–5.0 cm (20.0%). Mok and Sohn (2003) reported an average

ovarian tumour size of approximately 8.5 cm, while Hossain et al. (2010) reported tumour sizes predominantly within the 5.1–10.0 cm range, which is consistent with the present findings.^[17,24] When tumour size was compared according to histopathological diagnosis, benign tumours were more frequently within the 5.1–10.0 cm range, whereas malignant tumours were more commonly >10 cm. The difference between the benign and malignant groups was statistically significant ($p < 0.05$), consistent with the observation of Kawai et al. (2002).^[25] Hossain et al. (2010), however, found no significant association between tumour size and histological type.^[17]

Histopathologically, 54.3% of the tumours in the present study were benign, and 45.7% were malignant. Hossain et al. (2010) found 56.7% benign and 43.3% malignant lesions.^[17] However, Hartman et al. (2012) reported a higher proportion of benign tumours (71.8%)^[26], while Alcazar et al. (2009) reported a higher proportion of malignant tumours (68.0%).^[18] Choudhury et al. (2005) reported an even higher proportion of benign tumours (92.5%), indicating considerable variation among study populations.^[20]

In this study, among the benign tumours, serous cystadenoma was the most frequent histological type, whereas serous cystadenocarcinoma was the predominant malignant tumour. Hossain et al. (2010) similarly reported serous cystadenocarcinoma as the most common malignant tumour, although mucinous cystadenoma was the predominant benign lesion in their study.^[17]

In the present study, CA-125 showed a sensitivity of 68.8%, specificity of 84.2%, accuracy of 77.1%, positive predictive value

(PPV) of 78.6%, and negative predictive value (NPV) of 76.2%. Gungor et al. (2001) also reported both false-positive and false-negative results with CA-125 and noted that CA-125, together with ultrasonographic assessment, can contribute to the prediction of malignancy in adnexal masses.^[27] Hossain et al. (2010) reported a sensitivity of 76.9% and specificity of 94.1% at a higher CA-125 cut-off of 83.58 U/mL.^[17] Doppler indices also showed useful diagnostic performance. The pulsatility index (PI) demonstrated a sensitivity of 56.3%, specificity of 84.2%, accuracy of 71.4%, PPV of 75.0%, and NPV of 69.6%. Hossain et al. (2010) reported a moderate accuracy of 63.3% for PI at a cut-off of <1, although the relatively low PPV limited its usefulness as an isolated diagnostic parameter.^[17]

The resistance index (RI) showed a sensitivity of 43.8%, specificity of 89.5%, accuracy of 68.6%, PPV of 77.8%, and NPV of 65.4% in the present study. Thus, RI showed higher specificity but lower sensitivity than PI. Hossain et al. (2010) reported relatively high predictive values for RI at a cut-off of <0.5, while Gungor et al. (2001) reported a sensitivity of 70.3% and specificity of 90.0% using the same cut-off.^[17,27]

The novel index demonstrated the most favourable overall performance among the individual parameters in the present study. It showed a sensitivity of 75.0%, specificity of 84.2%, accuracy of 80.0%, PPV of 80.0%, and NPV of 80.0%. These findings are comparable with those of Hossain et al. (2010), who reported a sensitivity of 75.0%, specificity of 92.86%, accuracy of 83.33%, PPV of 92.31%, and NPV of 76.47%.^[17] Although the novel index is derived from CA-125, it showed slightly better overall

accuracy than CA-125 alone in the present study.

Overall, the findings suggest that CA-125 and Doppler indices provided useful diagnostic information, while the novel index showed promising overall performance in the preoperative evaluation of ovarian tumours. Doppler findings should therefore be interpreted together with tumour markers, conventional ultrasonography, and clinical features rather than used as a single diagnostic test.

CONCLUSION

This study demonstrated that colour Doppler sonography and serum CA-125 are useful complementary tools for the preoperative differentiation of benign and malignant ovarian tumours, with histopathology serving as the reference standard. Among the individual parameters evaluated, the novel index showed better overall diagnostic performance, particularly in terms of accuracy and negative predictive value, despite being derived from CA-125. Serum CA-125 also showed good diagnostic value, while PI had comparatively limited ability to predict malignancy. Overall, the findings suggest that combining clinical assessment with serum CA-125 and colour Doppler parameters may improve the preoperative evaluation of ovarian tumours.

However, further studies involving larger sample sizes are recommended to validate these findings and establish the clinical utility of the novel index.

CONFLICT OF INTEREST

None

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