

Clinico-Pathological Evaluation of Gynaecological Pelvic Masses: A Prospective Observational Study

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ABSTRACT

Introduction: Gynaecological abdominal and pelvic masses are a frequent clinical presentation, encompassing a broad spectrum of benign and malignant pathologies. Accurate preoperative differentiation is essential to optimise management, preserve fertility, and improve oncological outcomes.

Aim: To evaluate the clinical presentation, radiological characteristics, histopathological association, and diagnostic accuracy of tumour markers and Risk of Malignancy Index (RMI) in gynaecological pelvic masses.

Materials and Methods: This prospective observational study was conducted from February 2025 to February 2026, in the Department of Obstetrics and Gynaecology at Dhiraj Hospital, Vadodara, Gujarat. Thirty women aged 15-70 years with clinically and radiologically diagnosed pelvic masses were enrolled. All patients underwent detailed clinical evaluation, Ultrasonography (USG) as the primary imaging modality, and Magnetic Resonance Imaging (MRI) in selected cases. Serum tumour markers, including Cancer Antigen (CA-125), Carbohydrate Antigen (CA19-9), and Carcinoembryonic Antigen

(CEA), were assessed where indicated. Surgical management was performed, and histopathological examination served as the gold standard. Diagnostic performance indices of imaging, tumour markers, and RMI were calculated.

Results: The mean age of the patients was 41.1 ± 11.7 years, with the majority in the 41–50-year age group (12; 40%). The most common clinical findings were palpable pelvic or abdominopelvic mass (19; 63.3%), lower abdominal pain (10; 33.3%), and Abnormal Uterine Bleeding (AUB) (10; 33.3%). Uterine fibroids were the most frequent pathology (9; 30%). Among ovarian masses ($n = 17$), CA-125 was elevated in 83.3% (5/6) of malignant and 36.4% (4/11) of benign cases. High RMI (>200) was strongly associated with malignancy ($p = 0.0012$), showing a sensitivity of 83.33% (5/6) and specificity of 100% (11/11), with an overall diagnostic accuracy of 94.12% (16/17).

Conclusion: Comprehensive clinical evaluation combined with USG, tumour markers, and RMI enhances preoperative discrimination between benign and malignant pelvic masses, facilitating appropriate surgical planning and improved patient outcomes.

Keywords: Adnexal disease, Pelvic Inflammatory Disease, Sensitivity and specificity, Tomography, Ultrasonography, X-ray

INTRODUCTION

One of the most frequent gynaecological issues in women of all ages is adnexal and pelvic masses. Most of them are non-cancerous, but a large percentage of them are gynaecologic cancers such as ovarian neoplasia, which still continue to be a major cause of cancer-related morbidity and mortality among women worldwide [1]. The prevalence of pelvic masses is relatively higher in women of reproductive age; in the post-menopausal period, the risk of malignancy rises significantly [2].

Globally, ovarian cancer is the seventh most common cancer among women and the eighth leading cause of cancer-related mortality, with a five-year overall survival rate of less than 45% [3]. Therefore, it is crucial to differentiate the benign from the malignant nature of pelvic masses preoperatively for the appropriate clinical management, optimal surgical planning, fertility preservation in younger women, and timely referral to gynaecologic oncology centres when malignancy is suspected [4].

The preliminary diagnostic information from clinical history, physical examination, and laboratory investigations is of paramount importance, but imaging modalities are essential for characterising pelvic masses [5]. Of these, Transvaginal Ultrasonography (TVUS) is most widely used and accessible, is cost-effective, and is the most sensitive imaging modality [6]. The International Ovarian Tumour Analysis (IOTA) simple rules have further improved the pre-operative assessment of adnexal lesions using sonographic findings, in addition to menopausal status and tumour marker levels [7].

Serum markers such as CA-125, CEA, and CA19-9 can help to differentiate benign from malignant masses, particularly in complex masses, but may not be as reliably positive or negative as other tests due to the patient's age, menopausal status, and underlying pathology [8]. Despite the development of imaging and tumour marker evaluation, some of the benign lesions can be radiologically non-specific, mimicking malignancy, and early-stage malignancies can occasionally present with non-specific features, posing diagnostic challenges [9]. Gynaecological pelvic masses should be definitively diagnosed via histopathological examination [10].

Thus, the present prospective observational study was conducted to determine the clinical presentation, radiological features, and histopathologic spectrum of gynaecological pelvic masses and to determine the value of pre-operative imaging and tumour markers in distinguishing benign from malignant masses.

MATERIALS AND METHODS

The current prospective observational study was conducted in the Department of Obstetrics and Gynaecology at Dhiraj Hospital, Vadodara, Gujarat, from February 2025 to February 2026. A total of 30 female patients aged between 15 and 70 years, presenting with clinically and radiologically diagnosed pelvic masses, were enrolled in the study after obtaining informed consent. The institutional ethical committee approved the present study.

Eligible patients fulfilling the inclusion criteria during the study period were recruited using consecutive sampling until the desired sample size was achieved.

Inclusion and Exclusion criteria: Inclusion criteria comprised all female patients aged 15-70 years who presented with pelvic masses and subsequently underwent radiological evaluation and surgical management with histopathological confirmation. Exclusion criteria included patients with non-gynaecological masses, incomplete clinical or radiological records, or those who declined surgical intervention.

For each patient, a detailed clinical history and thorough general and pelvic examinations were performed. Radiological assessment was performed using USG as the primary imaging modality, and MRI was performed in selected cases to characterise complex or indeterminate lesions further. Serum tumour markers, including CA-125, CEA, were evaluated to help differentiate benign from malignant pelvic masses. Intraoperative findings were documented, and all surgical specimens underwent histopathological examination, which served as the gold standard for final diagnosis.

Risk of Malignancy Index (RMI) and CA125 in Ovarian Cancer Diagnosis [11]

The RMI-1 is a clinical scoring system used to estimate the likelihood that an ovarian mass or lesion is malignant (cancerous) rather than benign. RMI analysis was limited to ovarian masses.

The RMI incorporates the following components:

1. Cancer Antigen 125 (CA125):
2. Ultrasound (USG):
3. Menopausal Status:

RMI Calculation: The RMI was calculated using the following formula:

RMI= CA125 × USG score × Menopausal status

- **CA125:** The serum level (in U/mL).
- **USG score:** A score based on ultrasound findings:
 - 0 for a benign mass (e.g., simple cyst).
 - 1 for a suspicious mass (e.g., complex mass with some characteristics suggestive of malignancy).
 - 3 for a malignant mass (e.g., solid, irregular, multi-loculated with increased blood flow).
- **Menopausal status:**
 - 1 for premenopausal women.
 - 3 for postmenopausal women.

STATISTICAL ANALYSIS

The collected data were compiled and analysed using SPSS version 20. Demographic variables, clinical presentations, and histopathological patterns were summarised as frequencies and percentages. The diagnostic accuracy of preoperative imaging modalities and tumour markers was evaluated by calculating their sensitivity, specificity, Positive Predictive Value (PPV), and Negative Predictive Value (NPV).

RESULTS

[Table/Fig-1] showed that the mean age of patients was 41.1±11.7 years. Most cases were in the 41-50 years age group (40.00%). Most patients were premenopausal i.e., 22 (73.33%), whereas 8 (26.67%) were postmenopausal.

Age (in years)	Number of patients	Percentage (%)
17-30	6	20.00%
31-40	7	23.33%
41-50	12	40.00%
51-60	3	10.00%
> 60	2	6.67%
Total	30	100.00%
Mean±SD	41.1±11.7 years	

[Table/Fig-1]: Age distribution of patients with gynaecological pelvic masses.

[Table/Fig-2] showed that a pelvic or abdominopelvic mass was the most common finding (63.33%), while lower abdominal pain and AUB were each present in 33.33% of patients.

Sign/symptoms	Number of patients	Percentage (%)
Pelvic or abdominopelvic mass	19	63.33%
Adnexal fullness	5	16.67%
Tenderness	3	10.00%
Ascites	3	10.00%
Lower abdominal/pelvic pain	10	33.33%
Abnormal Uterine Bleeding (AUB), including menstrual irregularities and postmenopausal bleeding)	10	33.33%
Abdominal distension, bloating	3	10.00%
GI symptoms (dyspepsia, flatulence)	2	6.67%
Asymptomatic	2	6.67%
Infertility	3	10.00%

[Table/Fig-2]: Clinical signs and symptoms of patients with gynaecological pelvic masses.

The sensitivity was 83.33% indicating the USG diagnosis correctly detected approximately 83% of histopathologically confirmed malignant cases. The specificity was 95.83% , indicating a high ability to correctly identify benign lesions [Table/Fig-3].

USG diagnosis	HPE malignant	HPE benign	Total
Malignant/suspicious	5 (TP)	1 (FP)	6
Benign	1 (FN)	23 (TN)	24
Total	6	24	30

Statistic	Value	95% CI
Sensitivity	83.33%	35.88% to 99.58%
Specificity	95.83%	78.88% to 99.89%
Positive likelihood ratio	20	2.84 to 140.83
Negative likelihood ratio	0.17	0.03 to 1.04
Disease prevalence (*)	20.00%	7.71% to 38.57%
Positive Predictive Value (PPV) (*)	83.33%	41.52% to 97.24%
Negative Predictive Value (NPV) (*)	95.83%	79.32% to 99.28%
Accuracy (*)	93.33%	77.93% to 99.18%

[Table/Fig-3]: Diagnostic accuracy of ultrasonography (USG) in gynaecological pelvic masses.

*Note - The wide 95% Confidence Interval for sensitivity (35.88% to 99.58%) is an expected statistical consequence of the small cohort subset of histopathologically confirmed malignant cases (n=6). This wide interval indicates lower statistical precision for the isolated sensitivity metric, which has been explicitly noted as a study limitation

[Table/Fig-4] showed that uterine fibroids were the most common pelvic masses (30.00%).

Type of masses	No. of cases	Percentage (%)
Uterine fibroids	9	30.00%
Ovarian cystadenomas	5	16.67%
Endometriomas	3	10.00%
Dermoid cysts	3	10.00%
Malignant ovarian tumours	6	20.00%
Adenomyomas	2	6.67%
Tubo-ovarian abscesses	2	6.67%
Total	30	100.00%

[Table/Fig-4]: Distribution of types of gynaecological pelvic masses.

[Table/Fig-5] showed that among 17 ovarian masses (11 benign, 6 malignant), CA19-9 and CEA were elevated in fewer cases (17.65% and 11.76%, respectively).

[Table/Fig-6] showed that most malignant cases were in the high RMI category (>200), while benign cases were predominantly in the low and intermediate groups, with a statistically significant association

Tumour marker	Level range/status	Benign (n)	Malignant (n)	Total (n)	Percentage (%)
CA-125 (U/mL)	Normal (<35)	7	1	8	47.06%
	Raised (>35)	4	5	9	52.94%
CA19-9 (U/mL)	Normal (<37)	10	4	14	82.35%
	Raised (>37)	1	2	3	17.65%
CEA (ng/mL)	Normal (<2.5)	10	5	15	88.24%
	Raised (>2.5)	1	1	2	11.76%

[Table/Fig-5]: Tumour marker levels in patients with ovarian masses (17).

RMI category	Benign	Malignant	p-value
Low	7	0	0.0012*
Intermediate	4	1	
High (>200)	0	5	
Total	11	6	
Statistic	Value		95% CI
Sensitivity	83.33%		35.88% to 99.58%
Specificity	100.00%		71.51% to 100.00%
Disease prevalence	35.29%		14.21% to 61.67%
Positive Predictive Value (PPV)	100.00%		47.82% to 100.00%
Negative Predictive Value (NPV)	91.67%		64.76% to 98.50%
Accuracy	94.12%		71.31% to 99.85%

[Table/Fig-6]: Risk of Malignancy Index (RMI) categories and diagnostic accuracy.

*Pearson's Chi-Square test applied

*Note- The wide 95% Confidence Interval for sensitivity (35.88% to 99.58%) is an expected statistical consequence of the small cohort subset of histopathologically confirmed malignant cases (n=6); This wide interval indicates lower statistical precision for the isolated sensitivity metric, which has been explicitly noted as a study limitation

(p=0.0012). The RMI demonstrated high diagnostic performance, with 83.33% sensitivity, 100.00% specificity, and an overall accuracy of 94.12%. [Table/Fig-7] showed that hysterectomy was the most common procedure for uterine fibroids and adenomyomas.

Type of pelvic mass	Number of cases	Surgical management performed	Number of cases (n)	Percentage (%)
Uterine fibroids	9	Total abdominal hysterectomy (±BSO)	6	20.00%
		Myomectomy	3	10.00%
Ovarian cystadenomas	5	Ovarian cystectomy	3	10.00%
		Salpingo-oophorectomy	2	6.67%
Endometriomas	3	Ovarian cystectomy	3	10.00%
Dermoid cysts	3	Ovarian cystectomy	2	6.67%
		Salpingo-oophorectomy	1	3.33%
Malignant ovarian tumours	6	Staging laparotomy with TAH + BSO + omentectomy± lymphadenectomy	6	20.00%
Adenomyomas	2	Total abdominal hysterectomy	2	6.67%
Tubo-ovarian abscess	2	Drainage with salpingo-oophorectomy	2	6.67%
Total	30			100.00%

[Table/Fig-7]: Type of pelvic mass and surgical management performed (n = 30).

DISCUSSION

In the present study, Patients' mean age was 41.1±11.7 years, with the highest proportion in the age group 41-50 (40%). In agreement with this, Pillai SS et al., noted that the most common age range for pelvic masses was 40-49 years, and Rai R et al., found that adnexal masses were most prevalent in the reproductive and perimenopausal age groups [12,13].

The majority of patients in the present study were premenopausal (73.3%). According to Matalliotakis M et al., benign ovarian tumours occurred more often among premenopausal women, while malignant tumours were found significantly more often among those who were postmenopausal [9]. In the same way, Bandi S et al., showed a higher rate of malignant ovarian pathology in postmenopausal age groups, highlighting the relevance of carefully evaluating adnexal masses in this age group due to their greater malignant potential [14].

Mass (palpated clinically, either in the pelvis or the abdominopelvic region) was the most common presenting complaint in the present study, reported by 63.3% of patients, followed by lower abdominal pain (33.3%) and AUB (33.3%). Abdominal pain was reported in 54% of cases and abdominal mass in almost one-third of patients by Pillai SS et al., while abdominal pain and abdominal distention were reported to be the most common symptoms in women with adnexal masses by Rai R et al., [12,13].

Pathologically, uterine fibroids were the most frequently observed pelvic mass (30%) followed by ovarian cystadenomas (16.7%), malignant ovarian tumours (20%), and dermoid cysts/endometriomas (10% each). Pillai SS et al., also found leiomyoma to be the most common non-cancerous pelvic disease, and Rai R et al., found epithelial ovarian tumours to be the most common ovarian tumour [12,13].

In the present study, the serum CA-125 level was elevated in 83.3% of malignant and 36.4% of benign ovarian tumour cases, indicating good sensitivity and low specificity. Charkhchi P et al., similarly reported that there was an increase in the CA-125 level in both malignant ovarian tumours and in conditions like endometriosis and pelvic inflammatory disease. CA19-9 and CEA, however, were elevated primarily in mucinous tumours and dermoid cysts, thus being of limited but subtype-specific use. These results confirm the importance of always correlating tumour markers with imaging and clinical findings [15].

In the present study, the sensitivity, specificity, PPV, NPV, and diagnostic accuracy of the RMI-1 were 83.33%, 100%, 100%, 91.67%, and 94.12%, respectively, which has been shown to be highly diagnostic. Yamamoto Y et al., reported that combining serum CA-125, ultrasound findings, and menopausal status into RMI provided better diagnostic performance than individual parameters. RMI-4 showed the highest accuracy, with 86.8% sensitivity, 91.0% specificity, and 90.4% overall accuracy at a cutoff of 450 [16]. However, in the present study, the clinicoradiological and histopathological evaluation of the gynaecological pelvic masses in a tertiary care center is carried out, and the importance of the use of USG, tumour markers, MRI, and RMI scoring in improving the management and pre-operative diagnosis of gynaecological pelvic masses is emphasised.

Limitation(s)

- Small sample size;
- Single-centre study design;
- A limited number of malignant cases were included.

CONCLUSION(S)

Gynaecological pelvic masses present a broad spectrum of benign and malignant lesions, most frequently affecting women in the reproductive age group. USG combined with tumour markers and the RMI provided high diagnostic accuracy in distinguishing benign from malignant masses.

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