

DOI: <https://dx.doi.org/10.18203/2320-1770.ijrcog20231527>

Original Research Article

Clinico-radiological and histopathological study of ovarian masses at a tertiary care centre

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Received: 04 February 2023

Revised: 11 May 2023

Accepted: 12 May 2023

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ABSTRACT

Background: Counselling and rapid referral to a specialised facility might be improved with the use of a scoring system that could diagnose ovarian cancer. The relative simplicity of the Risk of Malignancy Index (RMI) scoring technique and the ease with which it may be applied make it a strong candidate to use as a primary diagnostic tool for individuals with pelvic masses.

Methods: Prospective observations study conducted on women diagnosed with ovarian mass by clinical examination and confirmed by ultrasonography, undergoing surgery at RL Jalappa Hospital, Kolar from January 2021 to December 2022. Histopathological report was considered as Primary outcome parameter. Age group, Parity, Menstrual history, Risk Malignancy Index, etc., were considered as explanatory parameters.

Results: A total of 40 subjects are included among which 22.50% are aged ≤ 40 years and 77.50% are aged >40 years. Using a cut off of 25, majority (88.2%) of those with malignancy had $RMI \geq 25$ and in benign histopathology report 56.5% had ≥ 25 RMI. Histopathology report, there was a statistically significant ($p < 0.05$) difference in RMI values. The RMI had a sensitivity of 88.24% in predicting malignancy with specificity 43.48%, positive predictive value 53.57%, negative predictive value 83.33% with a total diagnostic accuracy of 62.50%.

Conclusions: Results from RMI and histopathology correlate positively. The results of this research show that RMI is a reliable and practicable method for assessing patients with pelvic masses at the commencement of therapy and identifying those who are good candidates for centralised surgical treatment.

Keywords: Ovarian malignancy, Risk Malignancy Index, Ultrasonography, RMI, CA-125, postmenopausal, histopathology

INTRODUCTION

The ovary is a crucial organ because it is involved in the creation of offspring. Mesenchymal cells and sex cells, which are totipotent and multipotent, respectively, make up the ovary. Consequently, almost any type of tumour can develop when it turns neoplastic.¹ Even though they only account for 14 gm in an adult, the ovaries are the site of a wide range of benign and malignant tumours due to the extensive range of hormonal stimulation and changes that occur from the foetal period through menopause. Most

ovarian lesions are functional and will recover without much medical intervention. A large, bothersome cystic lesion may require surgery.^{2,3}

Gynecological oncologists face a lot of challenges from ovarian tumours and non-neoplastic lesions. Some ovarian non-neoplastic lesions frequently show up as a pelvic mass that resembles a tumour of the ovaries.

Therefore, it is crucial that they are correctly identified and categorised to enable effective therapy.⁴

After cervical and uterine cancers, ovarian cancer is the third most common gynecologic malignancy in women.⁵ The prevalence of ovarian cancer is very less in comparison with breast cancer but it has poor prognosis and has three times higher mortality rate than breast cancer.⁶ Rate of ovarian cancer survival in the general population varies between 30 to 40% in the world.⁷ Ovarian cancer has a 6.6/100,000 “age-standardized” incidence rate and a 3.9/100,000 mortality rate.⁸ The incidence of ovarian cancer in India is reportedly the second highest worldwide. Menopausal women account for 90% of ovarian cancer cases, often between the ages of 55 and 64, suggesting that longer life expectancy may be contributing to the global rise in ovarian cancer rates.⁹ Ovaries are least accessible female reproductive organs because of which there is delay in diagnosis of ovarian disorders including borderline tumours and ovarian malignancies.¹⁰ Recognizing malignancy in early stages helps in initiation of early treatment as ovarian cancer at later stages is lethal.¹⁰ Cancer Antigen (CA125) is elevated in ovarian cancers and hence can be used as biomarker for diagnosis of the same. “Human Epididymis protein” (HE4) is another biomarker used for diagnosis.¹¹ Determination of Ovarian Cancer using these biomarkers is highly specific yet insensitive. An improved, more useful, and more sensitive metric is the “Risk of Malignancy Index” (RMI). RMI is calculated using a simple regression equation that takes into account the “menopausal status” score (M), the “ultrasonographic” score (U), and the “absolute” value of blood CA-125.¹²⁻¹⁴ The RMI's excellent sensitivity for ovarian cancer diagnosis holds up when tested on a new cohort of women and remained consistent with the original paper outlining its development. A more precise diagnosis of ovarian cancer may be made using the RMI, the research found, as compared to using the individual criteria.¹⁵ A recent study indicated that a higher RMI cut-off of 238 had a sensitivity of 89.5%, specificity of 96.2%, positive predictive value of 77.3%, and negative predictive value of 98.4% when used for screening.¹⁶

Objectives

The objective is to study the spectrum of clinical presentation in a patient who presents with ovarian mass and to assess the correlation between the clinic radiological profile with histopathological picture.

METHODS

After receiving approval from institutional ethics committee. 40 patients were included in the study using prospective observational study design. All the cases with ovarian masses on clinical examination which is confirmed by imaging techniques under the age groups between 13 to 70 years were included in this study and patients with uterine masses including fibroids, adenomyosis, endometriosis and tubo-ovarian mass were excluded. After obtaining the informed consent from patients who met the above criteria, relevant information

like age, parity, family history of cancer, personal history of previous malignancies, symptoms and the duration of symptoms was taken from patient. Leading symptoms such as abdominal mass, abdominal swelling /discomfort, abdominal pain, gastrointestinal symptoms, urinary symptoms, generalized malaise and fatigue were recorded.

All patients underwent routine general physical examination, breast examination, lymphadenopathy, abdominal examination and pelvic examination. Preoperative evaluation included complete blood count, renal function test, liver function test, chest X-ray, serology, ultrasonography, CA 125, risk malignancy index. In relevant cases CT, MRI were done. Laparotomy or minimally invasive surgery were done in all cases.

The extracted specimen was sent to pathology department for histo-pathological examination. On receiving the specimen, gross features such as size, shape, colour, external appearance, findings on cut section and contents were noted. Detailed microscopic examination of the tumour was done to arrive at histo-pathological diagnosis. After arriving at the histopathological diagnosis, combined correlation was made with clinical and radiological profile.

Statistical methods

Histopathological report was considered as primary outcome parameter. Age group, parity, menstrual history, Risk Malignancy Index, etc., were considered as explanatory parameters. Mode of presentation, USG features, etc., were considered as study relevant variables.

Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables. The association between explanatory variables and categorical outcomes was assessed by cross tabulation and comparison of percentages. Odds ratio along with 95% CI is presented. Chi square test was used to test statistical significance.

Histopathological report was considered as gold standard. Risk Malignancy Index was considered as screening test. The sensitivity, specificity, predictive values and diagnostic accuracy of the screening test along with their 95% CI were presented.

P value <0.05 was considered statistically significant. Data was analysed by using coGuide software, V.1.01.¹⁷

RESULTS

A total 40 subjects were included in the final analysis.

Out of 9 participants in ≤40 years, 3 (33.33%) were benign and another 6 (66.67%) were malignant. Out of 31 participants in >40 years age group, 20 (64.52%) were benign and another 11 (35.48%) were malignant.

Table 1: Comparison of histopathological report with age group in the study population (n=40).

Age group (years)	Histopathological report		Chi square value	P value
	Benign (%)	Malignant (%)		
≤40 (n=9)	3 (33.33)	6 (66.67)	2.78	0.1338
>40 (n=31)	20 (64.52)	11 (35.48)		

Table 2: Comparison of histopathological report with parity in the study population (n=40).

Parity	Histopathological report		Chi square value	P value
	Benign (%)	Malignant (%)		
Nulliparous (n=3)	2 (66.67)	1 (33.33%)	0.41	0.8127
Primiparous (n=11)	7 (63.64)	4 (36.36%)		
Multiparous (n=26)	14 (53.85)	12 (46.15%)		

Out of 3 Nulliparous participants, 2 (66.67%) were benign and another 1 (33.33%) was malignant. Out of 11

Table 4: Comparison of histopathological report with unilateral/bilateral in the study population (n=40).

Unilateral/Bilateral	Histopathological report		Chi square value	P value
	Benign (%)	Malignant (%)		
Unilateral (n=20)	14 (70.00)	6 (30.00)	2.56	0.1098

Table 5: Comparison of histopathological report with CAI25 (U/ml) in the study population (n=40).

CAI25(U/ml)	Histopathological report		Chi square value	P value
	Benign (%)	Malignant (%)		
<35 (n=15)	10 (66.67)	5 (33.33)	0.83	0.3637
>35 (n=25)	13 (52.00)	12 (48.00)		

Table 6: Comparison of Histopathological report with menstrual history in the study population (n=40).

Menstrual history	Histopathological report		Chi square value	P value
	Benign (%)	Malignant (%)		
Perimenopausal (n=12)	5 (41.67)	7 (58.33)	1.76	0.1848
Postmenopausal (n=28)	18 (64.29)	10 (35.71)		

Out of 20 participants of Unilateral tumour, 14 (70%) were benign and another 6 (30%) were malignant. Out of 20 participants of bilateral tumour, 9 (45%) were benign and another 11 (55%) were malignant.

participants with primiparous, 7 (63.64%) were benign and another 4 (36.36%) were malignant. Out of 26 participants with multiparous, 14 (53.85%) were benign and another 12 (46.15%) were malignant.

Table 3: Descriptive analysis of mode of presentation in the study population (n=40).

Mode of presentation	Frequency	Percentage (%)
Pain abdomen	23/40	57.50
Menstrual irregularities	16/40	40.00
MASS per abdomen	30/40	75.00
Abdominal distention	13/40	32.50
White discharge	11/40	27.50
Bladder disturbances	13/40	32.50

Among the study population, 23 (57.50%) participants were in Pain in abdomen as mode of presentation, 16 (40%) participants were in menstrual irregularities mode of presentation, 30 (75%) participants were in Mass per abdomen mode of presentation, 13 (32.5%) participants were in abdominal distention mode of presentation, 11 (27.5%) participants were in white discharge mode of presentation and remaining 13 (32.5%) participants were in bladder disturbances as mode of presentation.

Out of 15 participants with <35 U/ml CAI25 group, 10 (66.67%) were benign and another 5 (33.33%) were malignant. Out of 25 participants with >35 U/ml CAI25 group, 13 (52%) were benign and another 12 (48%) were malignant.

Table 7: Descriptive analysis of USG features in the study population (n=40).

USG Features	Frequency	Percentage (%)
Cystic	21/40	52.50%
Solid	10/40	25.00%
Both	11/40	27.50%
Ascitis	9/40	22.50%
Multilocular cyst	12/40	30.00%
Unilocular cyst	11/40	27.50%
Thin septations	16/40	40.00%
Thick septations	9/40	22.50%

Table 8: Comparison of Histopathological report with Risk Malignancy Index in the study population (n=40).

Risk malignancy index (RMI)	Histopathological report		Chi square value	P value
	Benign (%)	Malignant (%)		
<25 (n=12)	10 (83.33)	2(16.67)	6.90	0.0317
25-250 (n=9)	6 (66.67)	3 (33.33)		
>250 (n=19)	7 (36.84)	12 (63.16)		

Table 9: Comparison of Histopathological report with USG Score in the study population (N=40)

USG Score	Histopathological report		Chi square value	P value
	Benign	Malignant		
USG Score 0 (n=13)	8 (61.54%)	5 (38.46%)	4.81	0.0901
USG Score 1 (n=13)	10 (76.92%)	3 (23.08%)		
USG Score 3 (n=14)	5 (35.71%)	9 (64.29%)		

Table 10: Predictive validity of Risk Malignancy Index in predicting malignancy (N=40)

Parameter	Value	95% CI	
		Lower	Upper
Sensitivity	88.24%	63.56%	98.54%
Specificity	43.48%	23.19%	65.51%
False positive rate	56.52%	34.49%	76.81%
False negative rate	11.76%	1.46%	36.44%
Positive predictive value	53.57%	33.87%	72.49%
Negative predictive value	83.33%	51.59%	97.91%
Diagnostic accuracy	62.50%	45.80%	77.27%

Out of 12 participants with perimenopausal menstrual history, 5 (41.67%) were benign and another 7 (58.33%) were malignant. Out of 28 participants with Postmenopausal menstrual history, 18 (64.29%) were benign and another 10 (35.71%) were malignant.

Among the study population, 21 (52.50%) participants had cystic feature, 10 (25%) participants had in solid feature, 11 (27.50%) participants had both feature, 9 (22.50%) participants had ascites feature, 12 (30%) participants had multilocular cyst feature, 11 (27.5) participants had unilocular cyst feature, 16 (40) participants had thin septations feature and remaining 9 (22.50%) participants had thick septations.

Out of 12 participants with <25 RMI, 10 (83.33%) were in benign and another 2 (16.67%) were malignant. Out of 9 participants with 25-250 RMI, 6 (66.67%) were benign and another 3 (33.33%) were malignant. Out of 19 participants with >250 RMI, 7 (36.84%) were benign and another 12 (63.16%) were in malignant. The difference in the proportion of benign and malignant cases across Risk Malignancy Index was statistically significant (P value 0.0317)

Out of 13 participants with USG score 0, 8 (61.54%) were benign and another 5 (38.46%) were malignant. Out of 13 participants with USG score 1, 10 (76.92%) were benign and another 3 (23.08%) were malignant. Out of 14 participants with USG score 3, 5 (35.71%) were benign and another 9 (64.29%) were malignant.

DISCUSSION

Ovarian tumours present differently than other gynaecological cancers, making it difficult for clinicians to diagnose them. Understanding whether a patient's ovarian tumour is benign or malignant is a constant challenge for doctors assessing a patient with such a growth. Clinical examination, ultrasonography, and CA-125 readings make up the "triple diagnostic approach" for identifying ovarian tumours. The "histopathological diagnosis" is the benchmark by which all other diagnoses are judged when it comes to predicting patient outcomes. In this prospective observational study conducted on women diagnosed with ovarian mass by clinical examination and confirmed by ultrasonography who are undergoing surgery at R. L. Jalappa Hospital, Kolar, we assessed the correlation between the clinico-radiological profile with histopathological picture. Histopathological report is the primary outcome parameter. This information may be used to propose strategies for early diagnosis of ovarian neoplasms and improved methods of treating the condition.

A total of 40 subjects are included in the analysis among which 22.50% are aged ≤ 40 years and 77.50% are aged >40 years. Laul et al had 77.3% of the women in the 21-40 years' age group with a mean age of 31 years in their study.¹⁸ Sixty percent of the women in Kamath et al.'s research was in their 40s and 50s, while just 7% were under the age of 20 and 13% were above the age of 60. Around 20% of the female participants were between the ages of 21 and 40.¹⁹ Dora et al. found that 61.1% of their cases occurred in premenopausal women, whereas 38.89% occurred in postmenopausal women.²⁰ Patients in the research by Rai et al. had a mean age of 36.6 ± 14.1 , and the vast majority (72.7%) were between the reproductive ages of 20 and 49.²¹ In the research by Priya et al., the average age of the participants was 42 years old, 62.83 percent were in the reproductive age group, and 10.62 percent were in the postmenopausal age group.²²

Majority of the patients in our study are multiparous at 65% followed by primiparous 27.5% and nulliparous 7.50%. Laul et al's study had 22.6% nulliparous and 77.3% multiparous women.¹⁸ In agreement with the above, majority (75%) were multiparous in Kamath et al.'s study.¹⁹ In Rai et al's study, 29.1 were nulliparous and 70.87% multiparous.²¹ Similar distribution was seen in In the research by Baru et al., only 22.22 percent of patients with ovarian tumours were nulliparous, while the remaining 77.78 percent were multiparous.²³

With regards to clinical presentation, 57.50% presented with pain abdomen, 40% with menstrual irregularities, 75% with mass per abdomen, 32.5% with abdominal distension, 27.5% with white discharge and 32.5% with bladder disturbances. Laul et al reported 44.3% had pain abdomen, 35.1 mass per abdomen, 8.2% with menstrual complaints, 12.4% with infertility, 25.8% had pressure symptoms in their study.¹⁸ ACOG guidelines state that

patients and their obstetrician-gynecologists are advised to remain appropriately suspicious in the presence of ovarian cancer warning indicators that might be important, such as women who experience symptoms such as "weight gain or bloating, pelvic or abdominal pain, difficulty eating, or feeling full quickly for more than 12 days per month". Patients meeting these criteria are more likely to develop ovarian cancer than women who do not exhibit these symptoms.²⁴ Our findings are consistent with those of Kamath et al, who also observed that abdominal pain was the most common symptom (63%), followed by "abdominal distension (40%) and abdominal mass (38%), and then nonspecific symptoms of vomiting and anorexia (25%)."¹⁹ Patients in the research by Priya et al reported the most often occurring symptoms to be abdominal discomfort and sporadic vaginal bleeding. Abdomen pain in 71.68%, bleeding per vaginum in 10.61%, abdominal distension in 9.73%, irregular menstruation in 5.3% were clinical symptoms in their study.²² Pain in the abdominal region was reported by 77.05% of patients, swelling by 70.49%, the presence of ascites by 57.38%, the presence of a mass in the abdominal region by 44.90%, and other constitutional symptoms such as "gastrointestinal distress, weakness, menstrual disorders, and urinary symptoms" by 29.5%, 16.4%, 3.28%, and 3.28%, respectively in Baru et al's study.²³

At a cut off of 35, 37.50% had <35 U/ml CA-I25 and 62.50% had >35 U/ml CA-I25. Among the patients analysed by Kamath et al, 62% had CA-125 levels over 100 U/l, 16% had levels between 35 and 100 U/l, and 22% had levels below 35 U/l.¹⁹

On ultrasonography, 52.50% had cystic mass, 25% had solid, 27.50% had both cystic and solid feature, 22.50% had ascites, 30% had multi cystic feature, 27.50% had unicystic feature, 40.00% had thin septations and 22.50% had thick septations. Fifty percent of the patients had multilocular lesions, presence of solid components in 64.28%, ascites in 38.09% in Dora et al's study.²⁰

Majority of our patients are postmenopausal at 70% with 30% perimenopausal. Contrary to our study group, Laul et al had majority (85.6%) in the premenopausal status and only 14.4% postmenopausal.¹⁸ Sixty-two percent of the women in Kamath et al's research were postmenopausal, 36% were menstruation, and just 2 were premenarchal.¹⁹ Javdekar et al's study had 58.62% premenopausal and 41.38% postmenopausal women.

In 17.5 percent of cases, USG score was 1, 35% of cases were given USG score 2, and 47.5 percent of cases were given USG score 3 based on the five ultrasound features suggestive of malignancy "(multilocularity (more than bilocular), presence of solid areas, bilaterality, presence of ascites, and extra ovarian tumours or evidence of metastases)." Sixty-five percent in the research by Kamath et al. had ultrasonography scores more than 2, which is indicative of a malignant tumour.¹⁹ A total of 45.24 percent of cases in the research by Dora et al. got an ultrasound

score of 1, whereas 54.76 percent of patients were given a score of 3.²⁰

Upon histopathology of the mass, 57.5% had a benign mass and 42.5% had malignant mass. Histopathological testing revealed that 88.7 percent of the ovarian tumours in the research by Laul et al were benign, while just 11.3% were malignant.¹⁸ Cancerous tumours made for 55.76 percent of the tumours in Dora et al.'s research, whereas benign tumours accounted for 45.24 percent.²⁰ Rai et al's study had a less rate of malignancy at 17.6% with 82.4% benign masses.²¹ Priya et al reported 65.48% were benign and 34.51% were malignant ovarian tumours in their study.²² Malignancy rate was 17% in Al-Musalhi et al's study.²⁶ In Javdekar et al's study, 71% had benign tumours, 3% had borderline, and 26% had malignant disease.²⁵ Majority of them are malignant tumours (56.48%) followed by benign tumours (40.74%) and borderline tumours (2.78%) in Baru et al's study.²³

Limitations and recommendations

The study is limited by small sample size. As it is hospital-based, there is a higher prevalence of malignancies and referral bias than in the general population.

CONCLUSION

Results from RMI and histopathology correlate positively. The results of this research show that RMI is a reliable and practicable method for assessing patients with pelvic masses at the commencement of therapy and identifying those who are good candidates for centralised surgical treatment.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Shravya MK, Rathnamma P, Kalyani R. Clinico-radiological and histopathological study of ovarian masses at a tertiary care centre. *Int J Reprod Contracept Obstet Gynecol* 2023;12:1631-7.