Research Article

Risk of Malignancy Index (RMI) Assessment in Pre and Postmenopausal Women with Adnexal Masses: A Cross-Sectional Study

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Abstract

Background: Adnexal mass is a common presentation in gynecological settings. Differentiation between benign and malignant tumors is crucial for deciding the proper place and type of treatment. The RMI is considered a good and reliable tool in pre-operative differentiation of ovarian tumors, but limited work has been done on this tool in low-resource settings.

Objective: To assess the diagnostic accuracy of Risk of malignancy index in differentiating benign from malignant ovarian tumors.

Methods: This cross-sectional study was conducted in Department of Obstetrics & Gynaecology at Central Park Teaching Hospital, Lahore. Eighty females between 30-80 years, admitted with adnexal mass in the Department of Obstetrics & Gynaecology at Teaching Hospital, Lahore from October 1st to 30th September, 2023 were enrolled. RMI was calculated and findings were compared with histopathology.

Results: Among enrolled 80 females with adnexal mass the mean age of females was 43.70 ± 8.21 years. The mean BMI was 30.60 ± 5.68 kg/m^2. The mean duration of post-menopausal bleeding was 14.50 ± 6.22 months. The mean RMI of females was 212.95 ± 159.76. The Sensitivity of RMI was 100%, specificity was 90.6%, PPV was 72.7%, NPV was 100%, and diagnostic accuracy was 92.5% taking histopathological findings as gold standard.

Conclusion: Thus, RMI is found to be a reliable tool for the diagnosis of ovarian malignancy in females with suspicious adnexal mass.

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Introduction

The death rate for women with gynaecological malignancies is greatest for ovarian cancer. Furthermore, it is the sixth leading cause of death among women.[1] The majority of patients are often discovered at an advanced stage, resulting in unfavorable disease outcomes. In 2020, the incidence of ovarian malignancies was estimated to be about 21,750, accounting for nearly 1.2% of the total number of malignancies. The projected mortality count associated with the phenomenon amounts to 13,940. It is anticipated that the 5-year relative survival rate will be 48.6%.[2] In the age-compatible cohort studies it was shown that serous tumours were the most prevalent (58.6%), followed by mucinous tumours (17.2%) and teratomas (12%). This tendency is also seen in many researches, conducted in Pakistan, as well as in other regions throughout the globe.[3-5]

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Pakistan currently lacks a comprehensive cancer registry, despite the presence of two registers known as the Punjab registry and the Karachi cancer registry. However, both registries receive insufficient upkeep owing to limited finances. Ovarian cancer has been identified as the most often reported gynaecological malignancy in Pakistan, based on investigations conducted at different institutions[6,7]. Research conducted in India and Bangladesh has identified cervical cancer as the commonest form of malignancy in these regions.[8,9] Gynaecological cancer in Pakistan is subject to underreporting as a result of a multitude of causes. Accurate assessment of disease burden necessitates the availability of cancer registry and population-based data of superior quality. The implementation of evidence-based control programs in nations with a high illness burden will facilitate the development of effective strategies.[10]

According to current research findings, there is evidence to suggest that an elevated presence of both CA-125 and HE4 biomarkers might potentially indicate the presence of malignant ovarian tumours. This observation holds promise for the development of a valuable diagnostic tool in the next years. The use of CA-125 levels extends to the calculation of the risk of malignancy index (RMI), which incorporates both transvaginal ultrasound (TVUS) results and menopausal state. RMI is calculated by using the formula of multiplying the ultrasound scan score, the menopausal status and the serum CA125 level (IU/ml). RMI= U X M X CA125.

RM1 less than 25 is low risk.

RMI 25-250 is moderate risk.

RMI > 250 is high risk.

Ultrasound score 0,1,3 for multilocular cyst, solid areas, metastasis, ascites, and bilateral lesions. M score = premenupause scores. Menopausal score was assigned as 1 if premenopausal and 3 if female having postmenopausal status. An RMI value over 200 is correlated with a significantly elevated likelihood of malignancy, with a specificity of 87%. [11]

This study aims to find the role of RMI in differentiation of malignant and benign ovarian lesions, in women of low resource settings. In gynecological setting, women presenting with adnexal mass diagnosed on ultrasound is common issue but mostly for differentiation of type of lesion whether benign or malignant, they undergo invasive procedures, including biopsy, which has its own hazards and require time, money & expertise. Therefore, a non-invasive and inexpensive tool such as risk for malignancy index is a good and reliable way to better differentiate malignant and benign lesions. It can be used in peripheries, as not much expertise are required. However, limited work has been done on the use of this tool. Therefore, we conducted this study and obtained findings to see whether RMI can be implemented in local population or not.

Methods

This cross-sectional study was conducted in Department of Obstructs & Gynaecology, at Teaching Hospital, Lahore from October 1st to 30th September, 2023; Sample size of 80 cases was calculated with 95% confidence level, 11% margin of error and percentage of malignant ovarian lesion i.e. 49.18% n females with adnexal mass.

After taking informed consent women between 30-80 years were enrolled according to inclusion criteria by non-probability, consecutive sampling; demographics were noted including age, BMI, marital status, presenting complaint, menopausal status, parity, education, socioeconomic status. Ultrasound done by senior sonologist having 4 years' experience, CA125 report was assessed and RMI was calculated. Menopausal status was noted, and menopause was defined as cessation of menstrual cycle for ≥ 1 year. A cut-off level of ≥ 200 was considered as malignant mass. Women underwent staging laparotomy by senior gynecologist in liaison with surgeon and sample sent for histopathology to the pathology department for confirmation of type of ovarian lesion. Reports were assessed and final findings were recorded. All the data were recorded in proforma.

Data were analyzed in SPSS version 25. The 2×2 contingency tables were generated to calculate sensitivity and specificity, along with positive and negative predictive value and the diagnostic accuracy of RMI was calculated. Sensitivity was defined as the percentage of patients with ovarian malignancy and having a positive test result, while specificity as the percentage of women with benign ovarian masses and having a negative test result. The positive predictive value was defined as the percentage of participants with a positive test result having

borderline or malignant ovarian disease.

Results

In this study, 80 females were enrolled with adnexal masses. The mean age of females was 43.70 ± 8.21 years. The mean BMI was 30.60 ± 5.68 kg/m^2. Out of 80 females, 74 (92.5%) were married. Out of 80 females, 10 (12.5%) were nulliparous, 18 (22.5%) were primiparous and 52(65.0%) were multiparous. The mean duration of postmenopausal bleeding was 14.50 ± 6.22 months. Out of 80 females, 21 (26.3%) were illiterate, 19 (23.8%) were under matric, 24 (30.0%) were undergraduate and 16 (20.0%) were postgraduate. Out of 80 females, 27 (33.8%) belonged to low socioeconomic status, 34 (42.5%) belonged to middle class while 19 (23.8%) were from high class. Only 2 (2.5%) females had non-specific symptoms at presentation, while 32 (40.0%) had abdominal pain, 6 (7.5%) had abdominal mass on clinical examination while 40 (50%) females had abdominal pain along with abdominal mass. Out of 80 females, 70 (87.5%) were premenopausal and 10 (12.5%) were post-menopausal. The mean RMI of females was 212.95 ± 159.76. (Table-1)

Serous cystadenoma was present in 32 (40%) cases, 8(10) females had mucinous cystadenoma, 6(7.5%) had dermoid cyst, 16 (20%) had endometrioma, 6 (7.5%) had high grade serous cyst adenocarcinoma, 2 (2.5%) had mucinous cystadenocarcinoma, 8(10%) had endometroid adenocarcinoma and 2 (2.5%) had functional ovaries. (Figure-1)

Table 1: *Basic information*

Feature	Mean ± SD, f (%)
N	80
Age (years)	43.70 ± 8.21
BMI (kg/m^2)	30.60 ± 5.68
Marital status	
Married	74 (92.5%)
Unmarried	6 (7.5%)
Parity of females	
Nulliparous	10 (12.5%)
Primiparous	18 (22.5%)
Multiparous	52 (65.0%)
Duration of symptoms (months)	14.50 ± 6.22
Education	
Illiterate	21 (26.3%)
Under matric	19 (23.8%)
Undergraduate	24 (30.0%)
Postgraduate	16 (20.0%)
Socioeconomic status	
Low	27 (33.8%)
Middle	34 (42.5%)
High	19 (23.8%)
Presenting complaint	
Nonspecific	2 (2.5%)
Pain abdomen	32 (40.0%)
Mass abdomen	6 (7.5%)
Pain abdomen and mass abdomen	40 (50%)
Menopausal status	
Premenopausal	70 (87.5%)
Postmenopausal	10 (12.5%)
Risk of malignancy index	212.95 ± 159.76

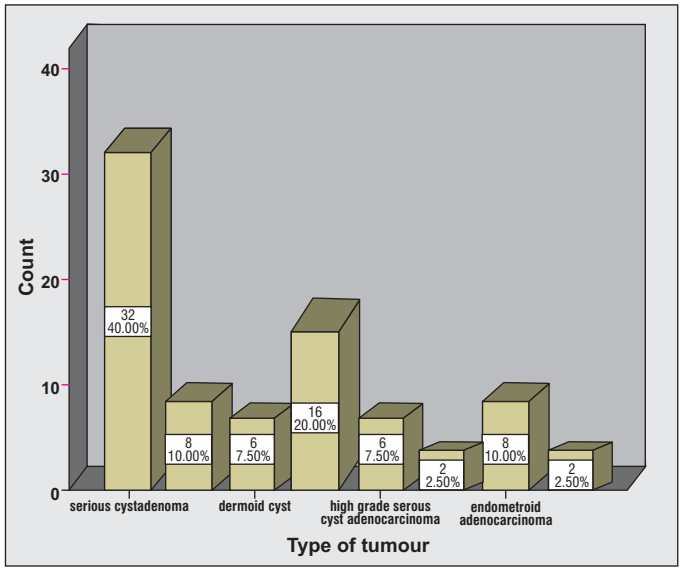

Figure 1: *Distribution of type of lesion observed on histopathology*

The Sensitivity of RMI was 100%, specificity was 90.6%, PPV was 72.7%, NPV was 100%, and diagnostic accuracy was 92.5% taking histopathological findings as gold standard. (Table 2)

Table 2: *Diagnostic accuracy of RMI against histopathology*

		Histopathology		Total
		Positive	Negative	
RMI status	Positive	16	6	22
	Negative	0	58	58
Total		16	64	80

Sensitivity = 100%, specificity = 90.6%, PPV = 72.7%, NPV = 100%, diagnostic accuracy = 92.5%.

Discussion

Ovarian malignancy ranks as the second most common cancer affecting the female reproductive system and

is the primary cause of mortality among gynecologic malignancies.[12-14] The occurrence and frequency of ovarian cancer exhibit regional disparities throughout various geographic regions of the world. The examination of trends in India indicates a consistent rise in the age-standardized incidence of ovarian cancer, with rates ranging from 0.26% to 2.44% per year across several regional registries.[15] The current study demonstrated RMI's sensitivity to be at 100%, although its specificity was only at 90.6%. The positive predictive value (PPV) was identified 72.7%, while the NPV was found to be 100%. When compared to the gold standard of histological findings, RMI was shown to have a diagnosis accuracy of 92.5%.

In a research done by Javdekar et al., it was shown that an RMI value of more than 200 exhibited a sensitivity of 70.5%, and specificity of 87.8%, while a positive predictive value (PPV) of 70.5%, and negative predictive value (NPV) of 87.8%. There was no statistically significant connection seen between RMI and disease state in the case of mucinous tumours.[16] According to Morgante et al. (1999), their study revealed that RMI 2 exhibited more reliability in distinguishing between benign and malignant ovarian illness compared to RMI[1]. A study conducted by Khawla Al Musalhi et al. examined a cohort of 361 patients who were handled sequentially. The researchers used RMI cut-off values of ≥200, compared with CA 125. The analysis yielded that the CA-125 had higher sensitivity in identifying ovarian malignancies in contrast to the RMI (69% versus 57%), but RMI was found to have higher specificity in excluding benign ovarian lesions compared to CA-125 (81% versus 68%).[17]

In their research, Shekhar et al. (2019) discovered that an RMI value greater than 200 exhibited a sensitivity of 68.57%, specificity of 92.17%, positive predictive value (PPV) of 64.86%, and negative predictive value (NPV) of 93.25%.[18] Yelikar et al. (2016) conducted a study that revealed that RMI demonstrated superior sensitivity (85.71%), specificity (85.07%), positive predictive value (PPV) (75%), negative predictive value (NPV) (91.93%), and accuracy (82.29%) when compared to the validity of different parameters. The researchers concluded that the use of RMI (Risk of Malignancy Index) is a straightforward, beneficial, and highly dependable method for distinguishing between malignant and benign lesions in pre-operative settings. The method's simplicity and applicability in the first assessment of women presenting with adnexal masses provide it a favorable choice for routine clinical gynaecological practice.[19]

In 1990, the Risk of Malignancy Index (RMI) was introduced by Jacobs et al as a risk assessment tool that incorporates menopausal state, CA125 levels, and ultrasound features using a cut-off value of 200 to identify malignancies.[20] In 1996, Tingulstad et al. made modifications to the original RMI, and subsequently introduced RMI 2, and the RMI 3 was discovered in 1999, which included modifications to the scoring system for ultrasound score (U) and menopausal status (M)[21]. Yamamoto et al. (2009) introduced an updated version of the Risk of Malignancy Index (RMI), denoted as RMI 4, which includes tumour size (S) in criteria.[22,23]

The serum biomarker HE4 was presented as an innovative and encouraging measure and subsequently received clearance by the U.S. FDA for diagnosis and further monitoring of epithelial ovarian cancer.[24] The Food and Drug Administration (FDA) plays a crucial role in the oversight and regulation of ovarian cancer surveillance. A study conducted by Vincent Dochez et. Al. concluded that, the combination of CA125 and HE4 is a very effective & handy tool to diagnose ovarian cancers. In 2009, Moore et al. proposed an algorithm using biomarkers to assess the risk of malignancy in masses. This algorithm, known as ROMA, integrates the findings from two pilot studies and incorporates HE4, CA125, and menopausal state to create a risk score. Based on this score, the masses are classified into high or low risk for malignancy. The validation of the algorithm was later done in a clinical trial by the same researcher in 2019, which included women who presented with a pelvic mass. During the assessment of 184 individuals with pelvic masses, the diagnostic accuracy for distinguishing between benign and malignant cases was determined. The sensitivity for this distinction was found to be 90.0% at a specificity level of 76.7% for ROMA as compared to other biomarkers revealing sensitivity of 94.0% and specificity of 76.3%.[25,26]

In 2019, researchers used data of women with benign ovarian lesions and early-stage ovarian cancers, to create the Early-stage Ovarian Malignancy (EOM) score.[27] Parameters utilized in determining the RMI were also

used in determining the EOM score. This research indicated a strong ability for discrimination, as measured by an AUC of 0.88 for the receiver operating characteristic curve. Furthermore, the model showed signs of accurate calibration. The EOM score shows promise as a triage mechanism for referring patients to units with specialists in oncology, but further research is required to authenticate its diagnostic accuracy as well as clinical relevance.

Ovarian cancers may be difficult to distinguish, however, in the past 30 years, various diagnostic methods and multimodal tests have been developed and proposed to be used in clinical settings. These methods include the Risk of Malignancy Index (RMI) and the International Ovarian Tumour Analysis systems.[28,29] Predictive criteria used by these various diagnostic methods for ovarian cancer diagnosis are unique. The standard RMI takes into account a wide range of information, including menopausal status, fundamental ultrasonographic patterns, and blood CA-125, a reliable diagnostic for ovarian cancer.[30] Although the Simple Rules of the International Ovarian Tumour Analysis methodologies have shown a high degree of diagnostic performance, it is important to note that between 10–20% of the examinations had equivocal findings, requiring additional consultations with experts.[31,32] Due to limitations in the International Ovarian Tumour Analysis (IOTA) system's Simple Rules, the Risk of Malignancy Index (RMI) has remained the gold standard in determining whether a patient's ovarian illness can be reliably distinguished from benign conditions before surgery. The RMI's clarity and ability to guarantee results are primary factors in its popularity.[30]

Conclusion

RMI is found to be a reliable tool for diagnosis of ovarian malignancy in premenopausal as well as postmenopausal females with adnexal masses. Thus in future, we can apply RMI in local settings for the differentiation of malignant and benign ovarian lesions as a cost-effective tool. This will also be helpful in poor resource settings and females who remained underdiagnosed due to non-availability of expensive and expert tools. Further studies are needed with a larger sample size, to strengthen the results.

Ethical Approval: The Institutional Ethical & Review Board, Central Park Medical College approved this study vide letter No. CPMC/IRB-No/1436.

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Authors' Contribution:

RN: Conception & design, analysis & interpretation of data,

RN: Conception & design, drafting of article, critical revision for important intellectual content, final approval

TZ: Acquisition of data, drafting of article

SZ: Drafting of article, critical revision for important intellectual content,

RB: Analysis & interpretation of data, drafting of article, critical revision for final approval

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