ORIGINAL ARTICLE

Diagnostic Accuracy of Risk of Malignancy Index in Females Undergoing Surgery for Ovarian Mass: Cross Sectional Study

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ABSTRACT

Background: Ovarian cancer is a leading cause of death from gynecologic malignancies. The diagnosis of ovarian cancer is confirmed by examination of a biopsy usually removed during surgery.
Aim**:** To determine the diagnostic accuracy of risk of malignancy index (RMI) in patients undergoing open surgery for ovarian mass taking histopathology as gold standard.
Study design: Cross-sectional study.
Methodology: Patients (n=75) having were enrolled to conduct the present study at Department of Department of Obstetrics & Gynaecology, Jinnah Hospital Lahore-Pakistan for 6 months. Enrolled patients were informed and consent was taken. The collected data was analyzed statistically by using SPSS version 20. Sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of RMI was calculated by using 2X2 table taking histopathology as gold standard.
Results: The mean age of the patient was 43.87±11.539 years. The mean RMI of the patient was 201.81±148.939. The calculated sensitivity and specificity of RMI were 86.2% and 91.3% respectively. The calculated positive & negative predictive values of RMI were 86.2% and 91.3% respectively. The overall diagnostic accuracy of RMI was 89.3%.
Conclusion: RMI is accurate enough to differentiate malignant and benign ovarian masses that we can rely on RMI in future.
Keywords: Risk of Malignancy Index, Ovarian Masses, Malignant Tumor and Histopathology

INTRODUCTION

Ovarian malignancy is a silent killer, especially affecting women above 50 years. Although presentation is often vague and nonspecific, symptoms are definitely present. Therefore a proper bimanual examination and appropriate investigations should be done at the outset in post-menopausal women[1]. In the United States, the incidence of ovarian cancer is 33 cases per 100,000 women aged 50 years or older. The estimated lifetime risk is 1 case in 70 women, which is a 1.4% lifetime incidence[2].

A prospective case-control study of 1,709 women visiting primary care clinics found that the combination of bloating, increased abdominal size, and urinary symptoms was found in 43% of those with ovarian[3].

The scoring methods based on menopausal status, ultrasonographic examination and serum CA-125 yield much better results than the earlier mentioned individual parameters[4,5]. In many studies, cut off value of Risk of malignancy index was taken as 200 but according to RCOG guidelines, the cut off level is 250 for predicting malignancy since higher cut off level increased the detection rate of true negative cases[6,7]. The RMI I is the most effective for women with suspected ovarian cancer. The RMI is a product of the ultrasound scan score, the menopausal status and the serum CA-125 level (IU/mL) as follows: RMI = U x M x CA-125[4].

Differentiation between benign and malignant tumors is a critical step in handling such cases clinically. Many women with advanced ovarian carcinoma undergo suboptimal primary surgeries at local hospitals. The amount of tumor left after the primary cytoreductive surgery is one of the most important prognostic factors in ovarian cancers[8,9].

Rationale of this study is to determine the diagnostic accuracy of risk of malignancy index (RMI) in patients undergoing open surgery for ovarian mass. In literature, several studies revealed different diagnostic accuracy of RMI. Some showed that it is sensitive enough to diagnose positive cases but some studies have controversies. Through this study we want to confirm the diagnostic accuracy of RMI. So that most of the patients can be prevented from unnecessary surgeries which may help to reduce burden of hospital and patients.

The objective of the study was to determine the diagnostic accuracy of risk of malignancy index (RMI) in patients undergoing open surgery for ovarian mass taking histopathology as gold standard

METHODOLOGY

Patients (n=75) having were enrolled to conduct the present study at Department of Department of Obstetrics & Gynaecology, Jinnah Hospital Lahore-Pakistan after Hospital's Ethical Committee approval for 6 months. Enrolled patients were informed and consent was taken. Patients were asked for menopausal status and then ultrasonography was done by a single radiologist for evaluation. Then blood was drawn and sent to pathology lab of the hospital for evaluation of serum CA-125. RMI was calculated. Patients were labeled as positive or negative on the basis of RMI value. Female patients having ovarian masses were included in present study. Patients who failed to give informed consent, having secondary malignancy and pregnant females were excluded.

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Statistical analysis: Mean±SD for age whereas frequency and percentage were given for ultrasound score and menopausal status was given by SPSS version 20. Sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of RMI was calculated by using 2X2 table taking histopathology as gold standard

RESULTS

The mean age of all enrolled patients was 43.87±11.539 years. The mean serum CA125 of the patient was 59.73±22.68u/ml. The mean RMI of the patient was 201.81±148.939. The minimum RMI was 20 and maximum RMI was 45. Among 75 enrolled patients, distribution of ultrasonography score and menopausal status of females was summarized in Table-1.

Among 75 enrolled patients, distribution of subjects according to RMI score>200 and histopathology report of females was summarized in Table-2.

Summary of findings on RMI as well as histopathology were summarized in table-3. Out of 29 cases positive on histopathology, 25(86.2%) were truly positive on RMI while 4(13.8%) were negative for RMI. Out of 46 cases negative on histopathology, 4(8.7%) were positive on RMI while 42(91.3%) were truly negative for RMI. The calculated sensitivity and specificity of RMI were 86.2% and 91.3% respectively.

Table 1: Distribution of ultrasonography score and menopausal status

		Frequency	%age
Ultrasound score	Score of 1	29	38.7
	Score of 2-5	46	61.3
Menopausal status	Premenopausal	35	46.7
	Postmenopausal	40	53.3

Table-2: Distribution of females according to the RMI score>200 and Histopathology

		Frequency	%age
RMI>200	Yes	29	38.7
	No	46	61.3
Histopathology	Malignant	29	38.7
	Benign	46	61.3

Table-3: Comparison of RMI score with histopathology

		Histopathology		Total
		Yes	No	
RMI>200	Yes	25 (86.2%)	4 (8.7%)	29 (38.7%)
	No	4 (13.8%)	42 (91.3%)	46 (61.3%)
Total		29 (100%)	46 (100%)	75 (100%)
Sensitivity		86.2%		
Specificity		91.3%		
PPV		86.2%		
NPV		91.3%		
Diagnostic Accuracy		89.3%		

DISCUSSION

Ovarian cancer is a leading cause of death from gynecologic malignancies. Approximately 70% of ovarian cancers are diagnosed at advanced stage and only 30% of women with such cancers can expect to survive 5 years. While fewer than 20% of ovarian cancers are confined to the ovaries at diagnosis, the five-year survival of women with localized tumors exceeds 90%[10,11].

Several studies have demonstrated that ovarian cancer patients operated by a gynecologic oncologist are more likely to undergo accurate staging and optimal cytoreductive surgery compared to patients who are operated by general gynecologists[11,12].

The high specificity and sensitivity of the risk of malignancy indices makes them an ideal and simple way of triaging women for this purpose. Application of RMI in clinical practice would provide a rational basis for specialist referral of patients with malignant diseases before diagnostic surgery. The high specificity and sensitivity of the risk of malignancy index makes it an ideal and simple way of triaging women for this purpose[9].

Thus we planned to conduct this study to find whether RMI is applicable and useful in local population or not. We included total 75 females with ovarian masses. The mean age of the patient was 43.87±11.539 years.

On ultrasonography, 29(38.7%) females attained ultrasound score of 1 while 46(61.3%) females attained ultrasound score of 2-5. We observed that in our study, 35(46.67%) females had premenopausal status while 40(53.33%) females had postmenopausal status. In our study, the mean serum CA125 of the patient was 59.73±22.68u/ml.

In our study, we calculated the sensitivity and specificity of RMI were 86.2% and 91.3% respectively. The calculated positive and negative predictive values of RMI were 86.2% and 91.3% respectively. The overall diagnostic accuracy of RMI was 89.3%. The RMI showed a sensitivity of 91% and specificity of 88% with cutoff value of RMI i.e., 200[13]. However, another author reported the sensitivity of 71.7% and specificity of 80.5% with cutoff value of RMI i.e., 200[14].

Bouzari et al., showed a sensitivity of RMI as 91% and specificity of 88% with cutoff value of RMI i.e., 200.[13] However, Ulusoy et al., reported the sensitivity of 71.7% and specificity of 80.5% with cutoff value of RMI i.e., 200.[15] Mojgan Karimi et al., cutoff point of 90, an under-chart area 86.7, 79.36% sensitivity, 78.95% specificity, 58.44%, positive predictive value, 90.08% negative predictive value, and 78.93% accuracy, and a p value of 0.004[16].

Santosh et al showed that the sensitivity (72.5%), specificity (98.2%), positive predictive value (98.1%), negative predictive value (74.7%) and diagnostic accuracy (84.13%) for discriminating malignant and benign pelvic masses[17]. Faiza et al., found that for the patients undergoing surgery, the sensitivity of RMI was 91.3%, specificity 76.9%, PPV 87.5%, and NPV 83.3% for differentiation of malignant and benign tumors[16].

In another study on 182 women with pelvic masses indicated an RMI > 250 had a sensitivity of 88.5% for diagnosing invasive lesions[18]. In a systematic review, 116 diagnostic studies for adnexal malignancy were reviewed. The reported result showed that at the cut off point of 200, RMI has a sensitivity of 78% and specificity 87% for malignant mass diagnoses which is similar to our report[17].

Obeidat with his colleagues described that using a cut-off level of 200 to indicate malignancy, the RMI gave a

sensitivity of 90%, specificity of 89%, positive predictive value of 96%, and negative predictive value of 78%. Researchers concluded that RMI is able to correctly discriminate between malignant and benign pelvic masses. It is a simple scoring system that can be introduced easily into clinical practice to facilitate the selection of patients who would benefit from primary surgery[19].

CONCLUSION

Thus controversy has been proved through this study and it was revealed that RMI is accurate enough to differentiate malignant and benign ovarian masses that we can rely on RMI in future. Now we are able to recommend the screening of females with ovarian masses through RMI instead of going for interventional method.

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