

Diagnostic Accuracy of Risk of Malignancy Index (RMI) in Discrimination of Benign from Malignant Ovarian Masses

FARAH LIAQUAT¹, HAFIZA YASMEEN ABBAS², NAZISH ALI³, ALIYA WAHEED⁴, SAIRA GHAFOR⁵, ADILA TAHIR⁶

^{1,2}Senior Registrar, ³Assistant Professor, Department of Obstetrics & Gynaecology, Baqai Medical University Fatima Hospital, Karachi

^{4,5}Assistant Professors, Department of Obstetrics & Gynaecology, Jinnah Medical and Dental College, Karachi

⁶Senior Registrar Dow University of Health Sciences / Civil Hospital, Karachi

Correspondence to: Dr Farah Liaquat, E-mail: syedafarah2009@gmail.com, Cell +923462296860

ABSTRACT

Objective: - To determine the diagnostic accuracy of Risk of Malignancy Index (RMI) in discrimination of benign from malignant ovarian masses, taking histopathology as gold standard.

Study Design: Cross sectional study.

Place and Duration of Study: Obstetrics and Gynaecology Department of Baqai Medical University, Fatima Hospital, Karachi from 1st January 2019 to 30th June 2019.

Methodology: Two hundred and thirteen women with ultrasound report showing ovarian mass were included in this study. After detailed history and physical examination those suspected of having any ovarian mass was subjected to ultrasound abdomen and pelvis (TVS) and serum CA-125 testing. Scoring for each patient was calculated and malignant and benign was labelled. Surgical specimen was sent to histopathology and report of benign or malignant was recorded.

Results: 29.2% were malignant and using cut-off value of RMI > 200, sensitivity 90.2% and specificity 54.9%, positive predictive value 58.7%, negative predictive value 97.3% and accuracy was 85.9%.

Conclusion: The risk of malignancy index to be a valuable, reliable, and applicable method in the primary evaluation of patients with ovarian masses and a usable method in referral of relevant patients for centralized surgical treatment.

Key Words: Ovarian mass, Risk of malignancy index, CA125

INTRODUCTION

The prevalence of ovarian cancer varies in geographical locations and in the US and UK is between 3 and 7 times greater than in Japan. The ovarian mass is the second-most common gynecological malignancy in the developed countries and is the five most frequent causes of women's cancer death.^{1,2} The exact incidence in Pakistan is uncertain, but ovarian cancer is Pakistan's fourth largest cancer among women and is still advanced.³ The fourth most widely recorded female malignancy in Eastern India was ovarian. The 8th most common occurrence of ovarian cancer is in Iran.⁴ A Nepalese research has shown that 16% of gynaecology was caused by ovarian masses.⁵

Most ovarian masses/cysts are benign; 90% have benign features. Of the others, 2/3 at advanced stage III or IV are malignant.⁶ Not only primary, ovary is the ideal location for other metastatic abdominal cancers.² The 5 years survival is just 30%-40%, due to the lack of operation for most ovarian cancers.⁷ Late appearance is due to its unclear medical symptomatology. For the same cause, malignancy in women with ovarian mass should be suspected/excluded early.¹

Several modalities such as bimanual palpation, tumor-marker, ultrasound, magnetic resonance imaging and post-emission tomography for early detection of ovarian malignancy have also been established.⁸ Jacobs et al⁹ in 1990 developed and suggested use for the benign malignant determination of adnexal mass in conjunction with the risk of malignancy indexes (RMI) based on serum CA 125 menopausal and ultrasound findings. Based upon the findings, adnexal masses with use of RMI were assessed by benign malignancy (for RMI = 200, sensitivity and specificity were 85.4% and 96.9%). They also suggested that the RMI could be used to provide patients

with more relevant and effective surgical knowledge in oncology centres. The risk of malignancy is the measure recommended by Royal College of Obstetricians and Gynecologists and recommended a cut of >200 in a recent analysis by Geomini et al.¹⁰ Ulusoy et al¹ found 31% malignant masses at cut off >200 in their 296-patient sample, 71.7% sensitivity and 80.5% specificity. 47% of patients were malignant and RMI > 200 were susceptible, 84% and 77% in an Australian sample of 204 patients.⁴ A research was conducted in 2004 on RMI from Rawalpindi. They recorded 87% sensitivity and 88% speciality using cut-off points of 125 and believed RMI had been better at distinguishing between benign and malignant ovarian tumours.^{11,12}

Tumours from the surface epithelial are the typical variant on morphological grounds. Most of them are benign, but there has been also an increased incidence of malignancy.^{13,14} It's an alarming discovery here. Therefore, efforts should be made to recognise the factors of risk. Although different methodologies to distinguish benign from malignant ovarian masses have been studied above, RMI has been slightly studied in Pakistan. Therefore, our research aims to assess the usefulness of local citizens. This research can be useful for pre-operative patient counselling, preparing suitable procedures and surgery and preventing unnecessary surgery in benign conditions.

MATERIALS AND METHODS

This cross sectional study was conducted at Obstetrics and Gynaecology Department of Baqai Medical University, Fatima Hospital, Karachi from 1st January 2019 to 30th June 2019. After detailed history and physical examination those suspected of having any ovarian mass were subjected to ultrasound abdomen and pelvis (TVS) and serum CA-125

testing. Ultrasound was done from Radiology Department of Fatima Hospital Karachi by same sonologist and CA-125 from central laboratory, both free of cost. Scoring for each patient was calculated and malignant and benign was labelled and data was entered by postgraduate trainee. Surgical specimen was sent to histopathology department DUHS and histopathology report whether benign or malignant was recorded.

The data was analyzed through SPSS-27. Sensitivity and specificity of RMI in discriminating benign from malignant mass were determined using a cut-off value of 200, RMI >200 was considered as malignant while ≤200 considered as benign, computing a 2x2 table.

RESULTS

Most of the patients 137 (64.42%) were below and equal to 40 years of age. The average age of the women was 38.81±13.16. One hundred and fifty five (72.77%) were premenopausal and 58 (27.23%) postmenopausal. Most of the women were married 200 (93.90%). Regarding parity status of the women, 146 (68.54%) women were nullipara and 67 (31.46%) had para 1 to 3 (Table 1). 29.2% were malignant and using cut-off value of RMI > 200, sensitivity 90.2% and specificity 54.9%, positive predictive value 58.7%, negative predictive value 97.3% and accuracy was 85.9% (Table 2).

Table 1: Demographic information of the patients

| Variable | No. | % |
|-------------------|-----|-------|
| Age (years) | | |
| ≤40 | 137 | 64.42 |
| >40 | 76 | 35.68 |
| Menopausal status | | |
| Premanopausal | 155 | 72.77 |
| Postmenopausal | 58 | 27.23 |
| Parity | | |
| Nulliparous | 146 | 68.54 |
| Multiparous | 67 | 31.46 |
| Marital status | | |
| Married | 200 | 93.9 |
| Unmarried | 13 | 6.1 |

Table 2: Diagnostic accuracy of risk malignancy index in discrimination of benign from malignant ovarian mass

| Risk malignancy index | Histopathology | | Total |
|-----------------------|----------------|------------|------------|
| | Malignant | Benign | |
| Malignant (RMI >200) | 37 (TP) | 26 (FP) | 63(29.6%) |
| Benign (RMI ≤200) | 4 (FN) | 146 (TN) | 150(70.4%) |
| Total | 41(19.2%) | 172(80.8%) | 213 |

Sensitivity = 90.2%
 Specificity = 54.9%
 PPV = 58.7%
 NPV = 97.3%
 Accuracy = 85.9%

DISCUSSION

Over the past few decades, the prevalence of ovarian neoplasms has risen. Silent occurrence and slow development, apart from few successful early diagnostic approaches makes the mortality rate higher among gynaecological malignancies.¹⁵ The rate of cure could be as high as 80–90% and the mortality rate could be reduced to 50% in patients with ovarian cancer at stage I.¹⁶ For

prediction of prognosis and management of the ovarian neoplasm, a new early diagnostic approach is thus of great importance. Selective referral to specialist oncological centres for patients with high risk of malignancy is important because primary cyto-reduction is a major part of ovarian cancer prognostics.

A classification system for a combination of different clinical features is the risk of malignancy index. Diagnostic specificity for ovarian malignancy has been increased. In the original, Jacobs et al⁹, based on menopause, ultrasound morphs, and serum levels of CA-125, established a malignancy index of 85.4% and a specificity of 96.9%. This algorithm was evaluated with promising results in retro and prospective studies.¹⁷ Based on the findings, it may be more sensitive and precise in relation to the ultrasound and serum CA-125 to assess adnexal masses using RMI as benign or malignant.

The average age of women in the current study was 38.81±13.16 and the average age of CA-125 was 23.3 (IQR=86). Of 213 women, the premenopausal were 155 (72.77%) and the postmenopausal were 58 (27.23%). In terms of women's parity, 69% of them were nulliparous and 32% had paragraphs 1-3. The mean patient age of 39.9±9.3 years was observed in Bouzari et al.¹⁸ They were also pre-menopausal (161 women or 88.4%). Middle age study was 50±11.8 years in Moolthiya et al.¹⁹ The 121 cases were premenopausal (57.9%).

In this study, 29.2% is malignant with a cut-off value RMI >200, 90.2% and 54.9% with a positive forecast value of 58.7%, a negative predictive value of 97.3% with an accuracy of 85.9%. Ulusoy et al¹ found 31% malignant weights at >200, 71.7% sensitivity and 80.5% species in their sample of 296 patients. 47% is malignant with RMI >200 sensitivity 84% and specificity 77% in an Australian study of 204 patients.⁴ A research was conducted in 2004 on RMI from Rawalpindi with a cut-off of 125, they recorded 87% sensitivity and 88% specificity, stating that RMI was better discriminated against both benign and malignant ovarian tumours.¹²

According to findings from Jacobs et al⁹, the benign-malignant determination of adnexal masses by RMI was 85.4% and 96.9% respectively, for RMI = 200. In 2009, 116 adnexal malignancy diagnostic studies were analysed in a systemic analysis report by Geomini et al.¹⁰ The findings indicated that RMI has 78% sensitivity and 87% specificity for malignant mass diagnoses at the cut-off point of 200.

The simplicity of the approach is a very strong argument for the use of RMI in the primary assessment of ovarian patients. The RMI can be used by non-specialist gynaecologists and all gynaecologists in everyday clinical practise. In the participating departments, we noticed no problems with the method. In other words, the applicability of RMI is illustrated by high compliance with almost referenced for central operative care. We also assume that by using RMI, the time for the procedure has been better planed, the actual efficiency of surgery referred to and laparoscopy versus laparotomy, cross abdominal versus median abdominal incision scheduled.

CONCLUSION

The present study has demonstrated the risk of malignancy index to be a valuable, reliable, and applicable method in

the primary evaluation of patients with ovarian masses and a usable method in referral of relevant patients for centralized surgical treatment. Other models of preoperative evaluation should be developed to improve the detection of non-epithelial ovarian cancers, borderline ovarian tumours, and early stage invasive disease. Use of the methods in routine practice should be an important element of these methods.

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