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RETROSPECTIVE ANALYSIS OF PRE OPERATIVE EVALUATION OF OVARIAN MASSES USING RM1-1 AND RM1-2

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HOW TO CITE THIS ARTICLE:

Joylene Diana D' Almeida, Sujaya V. Rao. "Retrospective Analysis of Pre-operative Evaluation of Ovarian Masses Using RM1-1 and RM1-2". Journal of Evolution of Medical and Dental Sciences 2015; Vol. 4, Issue 61, July 30; Page: 10631-10637, DOI: 10.14260/jemds/2015/1535

ABSTRACT: Ovarian cancer is a commonly diagnosed and particularly deadly gynaecologic malignancy Worldwide. Among the gynecological malignancies ovarian cancer is usually diagnosed in late stages due to the lack of presenting symptoms and the lack of efficient and reliable screening test. The objective of this retrospective analysis study was to assess the accuracy of tumor marker CA 125 and RMI (Risk malignancy index) scoring one and two systems in predicting the risk in malignant ovarian masses **METHODS:** A retrospective analysis of a total of 300 patients with ovarian masses was done in terms of symptoms, ultrasound findings and menopausal status and CA 125 was done. After calculating the RMI one and two, a correlation with the post-operative histopathology of the ovarian masses was done. **RESULTS:** The sensitivity of tumor marker CA 125, RMI 1 scoring and RMI 2 scoring in predicting malignancy was found to be 60, 75 and 60 percent respectively. The specificity value of tumor marker CA 125, RMI 1 scoring and RMI 2 scoring in prediction was found to be 88, 96 and 92 percent respectively. The negative predictive value of tumor marker CA 125, RMI 1 scoring and RMI 2 scoring in malignancy assessment was found to be 91.6, 96 and 92 percent respectively. **CONCLUSION:** This study showed that though CA 125, RMI ONE AND TWO systems are of use in assessing the risk of malignancy in ovarian masses, RMI I had the highest specificity, sensitivity and negative predictive value of the three. Whenever in doubt of the risk of malignancy, it is better to include RMI ONE scoring as a part of preliminary assessment of ovarian masses.

KEYWORDS: Ovarian mass and RMI one and two.

INTRODUCTION: Ovarian cancer is the one of the common cancer among females of India and continues to present at an advanced stage.¹ Japan and Asian countries have rates of 2–6.5 new cases per 100,000 women per year.² Ovarian carcinoma represents the sixth most common female cancer and the fourth leading cause of death due to cancers in women and is seen predominantly after 3rd decade.³

Ovarian cancer ranks among the top ten diagnosed cancers and top five deadliest cancers in Most countries.⁴ In ovarian cancer, best outcomes for patients can be achieved when patients are treated in tertiary centers by a multidisciplinary team led by a gynecological oncologist.

Suboptimal outcomes are achieved in countries where referral of ovarian cancer patients is problematic. Complication rates are higher (~30%) and Survival outcomes are lower (~10%) when a prompt referral of the patient is deferred. An accurate assessment of ovarian cancer burden is essential as incidence data are used for many purposes including to generate hypotheses regarding etiology, allocate resources and funding toward new treatment discovery and clinical trials, and determine which populations of women may benefit from more education or greater surveillance for the disease.⁵ CA 125 is a well-known tumor marker used in the risk assessment of ovarian cancer.

80% of ovarian cancer CA- 125 positive and 30% - 50% of patients with stage 1 ovarian cancer present with negative CA 125.

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Assessment of the Tumor Marker CA 125 however has shown to have certain limitations:

1. Low specificity—it can be Elevated in a large number of benign conditions like endometriosis and pelvic inflammatory disease.
2. Sensitivity is low in early stage ovarian cancer—it is seen that half of patients with stage 1 ovarian cancer are CA125 negative.

A simple algorithm called "risk of malignancy index" (RMI 1) was reported by Jacobs⁵. It is a simple scoring system. The risk of malignancy index (RMI) is said to be a better diagnostic marker as compared to CA 125. It has a high specificity and sensitivity in differentiating ovarian cancer from ovarian benign lesions. Jacobs et al reported that If RMI >200 was taken as a cutoff point, it had a Sensitivity of 85% and Specificity of 97%. He also stated that risk of malignancy index scoring (RMI) correctly selects 85% of ovarian cancers and if used accurately for referral only 3% of referred cases will be benign.

The following were the aim and Objectives of this Retrospective Analysis using Histopathology Study:

1. To assess the sensitivity and specificity of CA 125 in predicting malignancy in ovarian masses.
2. To assess the sensitivity and specificity of RMI 1 and RMI 2 in predicting malignancy in ovarian Masses.
3. To assess the positive predictive value and the negative predictive value of CA 125, RMI 1 and RMI 2.

MATERIALS AND METHODS: This study was done in the department of Obstetrics and Gynecology, Father Muller Medical College hospital, Mangalore from July 2012 to January 2014 in collaboration with department of Pathology and Gynecology. The study was retrospective observational study.

A total of 300 patients attending the OBG Department with ovarian masses at the time of admission were studied. The patients were of differing parity and ages and were evaluated based on their symptoms, ultrasound evaluation of the ovarian mass, menopausal status and RMI scoring. All patients underwent a staging Laparotomy and subsequently a correlation with their histopathology reports of the resected ovarian mass was done.

To increase the sensitivity and specificity of CA 125 for early detection of ovarian cancer, a combination of serum CA 125 with ultrasonography and menopausal status, designated as risk of malignancy index (RMI) 1 and 2 for each patient, was calculated:

Criteria for Postmenopausal Women:

- Amenorrhea > 1 year, or
- Women over 50 years of age with previous hysterectomy.

Ultrasound Findings Suggestive of Malignancy:

- Multiloculated cysts.
- Evidence of solid areas.
- Evidence of metastases.
- Presence of ascites.
- Bilateral lesions.

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Risk of malignancy index-one (RMI 1) Jacobs et al.⁵

Criteria	Scoring system
Menopausal status (A)	
Premenopausal	1
Postmenopausal	3
Ultrasound features (B)	
Multiloculated	No feature = 0
Solid areas	One feature = 1
Bilateral	>1 feature = 3
Ascites	
Metastases	
Serum CA 125 (C)	Absolute level
Risk of Malignancy Index (RMI) = A x B x C	

Table 1

Risk of malignancy index – two (RMI 2) Tinglusted et al (1996)⁶:

1. No 0 score if no ultrasound findings.
2. Only 2 levels for ultrasound findings.
3. Higher points given.

If a cutoff of > 200 was used to designate as malignant for both RMI 1 and RMI 2.

RESULTS AND DISCUSSION: In a study of 447 patients, Erik Soegaard⁷ et al reported a sensitivity of 70.6 percent and specificity of 89.3 percent. RMI one according to Erik et al had a positive predictive value of 66 percent and negative predictive value of 90 percent. In our study the prevalence of ovarian malignancy was 8.77 percent in the total population. The common age group of presentation was between 35 to 50 years. A significant proportion of patients presenting with ovarian masses both benign and malignant were nulliparous. Though malignancy was seen in extremes of age. 90 percent of the ovarian tumors that were diagnosed were found benign (Endometriotic, hemorrhagic, granulosa cell, benign epithelial and mature teratomas) and of the rest malignant (Cyst adenocarcinomas), 10 percent were also metastatic tumors from the gastrointestinal tract, as found in the post-operative histopathology.

Although abdominal pain was the most common presenting symptom, a significant proportion of our patients were asymptomatic at the time of presentation.

After analysis it was found that tumor marker CA 125, at cutoff level of 35 U/ml, had sensitivity of 60% and specificity of 88%. It had a low positive predictive value of only 55 percent in predicting malignancy. However its negative predictive value of 91.6 percent suggested it could still serve as a efficient screening modality to rule out ovarian malignancy.

It was noted that since in our population in south India the incidence of endometriosis is quite high, the chances of having false positives with CA 125 tumor marker assessment are also quite high. Ulusoy et al.⁸ reported that an RMI cut off 153, there was increased incidence of malignant tumors detected. In our study the cut off for RMI ONE and TWO was taken as 200.

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In the present study RMI 1 when used as a triage performed better than RMI 2 in predicting the risk of malignancy. It had a sensitivity of 75 percent and a specificity of 96 percent as compared to 60 percent sensitivity and 92 percent specificity of RMI 2. Hence RMI 1 proves to be a better tool for assessment of malignant ovarian masses. Overall when the need for risk assessment and triage arises, RMI 1 definitely provides an advantage over RMI 2 and CA 125, when used alone. The only catch is that tumor marker CA 125, at cutoff level of 35 U/ml, is a onetime non-invasive assessment whereas RMI scoring requires the additional use of ultrasound features. RMI scoring also demands an accurate USG assessment and is subject to inter observer variation. The positive predictive values of CA 125, RMI 1 and RMI 2 are 50, 75 and 60 percent respectively. The negative predictive values are 91.6, 96 and 92 percent respectively. This proves that overall these tests serve better in ruling out malignancy rather than confirmation of diagnosis. RMI 1 has the highest negative predictive value in ovarian malignancy. Contrary to our findings, Y.Yamamoto et al.⁹ however felt that RMI 2 had a higher sensitivity OF 90 percent over RMI 1 which had a sensitivity of 80 percent only.

The limitations of our study were that it was retrospective study aiming for a prospective validation in the future. We formed the impression that RMI one scoring system could prove promising in the adequate pre-operative planning (referral) and surgical performance in dealing with ovarian masses

Figure 1: Distribution of Ovarian Masses with Age

Figure 2

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Figure 3: Based on Histopathology

Figure 4: Based On Symptoms

Figure 5: Ultrasound Features

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Figure 6

Figure 7: Specificity Graph

Figure 8

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CONCLUSION: The risk of malignancy index (RMI) is a better diagnostic marker as compared to CA 125 alone because of its high specificity and sensitivity in differentiating ovarian cancer from ovarian benign lesions. It is a simple scoring system and, therefore, its application is recommended to evaluate ovarian masses in clinical practice. However in cases where an ultrasound is not feasible, a CA 125, at cutoff level of 35 U/ml, single assessment can be helpful in triage of ovarian masses, as it has a desirable negative predictive value.

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FINANCIAL OR OTHER

COMPETING INTERESTS: None

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Date of Submission: 07/07/2015.

Date of Peer Review: 08/07/2015.

Date of Acceptance: 23/07/2015.

Date of Publishing: 28/07/2015.