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Clinical Study on Diagnostic Accuracy of RMI

C. Shanthi[1], N.K. Mahalakshmi[2]

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Abstract

Objective: To compare the diagnostic accuracy of Risk of malignancy Index (RMI) with final histopathological diagnosis and to find out the role of RMI in preoperative evaluation of ovarian mass. *Materials and Methods:* Prospective study with 50 subjects who underwent surgical removal of ovarian tumour and performed histopathological examination in GRH, Madurai for a period of six months from January to June 2018. *Results*: The best cut off value of RMI was 100 with a sensitivity 96%, specificity 92% and accuracy 94%. *Conclusion*: The RMI is a simple scoring system and has a high sensitivity and specificity for the detection of malignant adnexal masses. Application of the RMI in clinical practice may provide a rational basis for speciduals to treat patients with adnexal masses before diagnostic surgery.

Keywords: Aadnexal masses; RMI scoring system; Tumour.

[1]Professor & Head, [2]Professor, Department of Obstetrics and Gynecolog, Government Rajaji Hospital (GRH), Madurai Medical College, Madurai, Tamil Nadu 625020, India.

Corresponding Author:
N.K. Mahalakshmi,
Professor, Department of Obstetrics and Gynecolog, Government Rajaji Hospital (GRH), Madurai Medical College, Madurai, Tamil Nadu 625020, India.
E-mail: rnkmaha@gmail.com

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Introduction

Gynaecological malignancies from ovarian cancer remain a leading cause of death in industralised countries. More than two-third of ovarian cancer cases are diagnosed when the disease has progressed to stage III or IV. Symptoms that are associated with ovarian cancer are typically nonspecific and the association is often recognized until the disease has advanced. Therefore recognizing it at the early stage is almost importance. Two-thirds of ovarian cases are diagnosed in women over the age of 55 years. In recent years the incidence of ovarian cancer is increasing in younger women. The increase in overall survival is associated with the management of patients with optimal debulking surgery for epithelial ovarian cancer. Also recent studies have shown that surgery by gynecologic oncologists improves survival. The aim of the study was to find out the diagnostic accuracy of RMI scoring system of ovarian mass.

Aim of the Study

- Role of RMI in Preoperative Evaluation of Ovarian Mass.
- To Compare the Diagnostic Accuracy of RMI With Final Histopathological Diagnosis.

Materials and Methods

50 subjects with adnexal masses admitted in GRH Madurai for a period of 6 months from January to june

2018. After obtained a full consent from the patients, a full history was obtained and a general and gynaecological examination was performed. Subjects then underwent a transvaginal ultrasound.

Adnexal masses were evaluated for sonographic, morphological criteria, bilaterality, solid areas, multiloculated, ascites and metastasis. A simple algorithm called Risk of malignancy Index (RMI) first reported by Jacobs. RMI is a simple method that can be applied directly into clinical practice rather than high priced or complex methods such as MRI or CT. The RMI is based on CA 125 level, the ultrasound score(U) and the menopausal status score (M). Serum samples of about 5 ml were collected preoperatively and serum CA 125 levels were measured.

Abnormal CA 125 level is defined as serum level >35 U/ml. Ultrasound score was defined as U=1 If 1 or 0 criteria fulfilled and U=3 if 2-5 are fulfilled.

Suspicious findinds on ultrasound are bilaterality, solid areas, multilocularity, papillary excrescens, thick wall and presence of ascites and evidence of metastasis. Additional imaging modalities such as CT scan or MRI were performed when ultrasound findings were doubtful.

Menopausal score was assigned as M=1, if premenopausal & M=3 for postmenopausal women.

Postmenopausal status was defined as more than 1 year of amenorrhea or age older than 50 years in women who had undergone hysterectomy. All other women were considered premenopausal. If the RMI score is less than 25 only less than 3% risk of cancer, if between 25-250, there is 20% risk of cancer. If the RMI score is more than 250, there is 75% chance of developing cancer.

The present study was designed to confirm the effectiveness of RMI to identify cases with high potential of ovarian malignancy in order to refer these patients to gynecologic oncologists.

After obtaining a written consent from the patients a full history was obtained and a general and gynaecological examination was performed. Subjects then underwent a trannsvaginal or transabdominal ultrasound.

The patients were divided into two groups according to RMI values.

Intra operative finding suggestive of benign or malignant such as presence or absence of ascites, unilateral or bilateral, mass fixed or mobile are documented. After removing the mass, on macroscopic cut section colour of the cystic fluid, presence or absence of septae, solid components noted and documented. Specimens of the adnexal mass were sent for histopathological examination. Histopathological results were analysed for correlation with RMI.

Bilateral ovarian cyst was noted in 5 cases-2 benign and 1 malignant. Ascites noted in 3 cases. Recurrent ovarian cyst in 2 women, one was a poly hysterectomised and another one with EHPVO. HPE findings were analysed to make a diagnosis.

Results

Table 1: Age Distribution

Age in years	No. of cases
< 30	3
31 - 45	7
45 - 60	25
> 60	15
Total	50

Table 2: RMI score distribution

RMI score	No. of cases
< 100	24
100 – 200	2
201 – 1000	6
> 1000	18
Total	50

Benign	No. of cases
Serious cystadenoma	13
Muinous Cystodenoma	6
Chocolate cyst	2
Follicular cyst	2
Dermoid cyst	2
Total	25

Malignant	No. of cases
Serum cystodeno carcinoma	15
Mucinonscystodeno carcinoma	6
Endometriodca	2
Germ cell tumour	2
Total	25

Histopathological report	
Benign	**Malignant**
24	1
2	23
26	24

Results	Percentage
Sensitivity	96
Specificity	92
Positive pred. value	92.3
Negative pred. value	95.8
Accuracy	94

Discussion

The aim of this study was to determine if the three versions of RMI, which combines serum CA-125 levels, ultrasound findings, and menopausal status can distinguish between benign and malignant adnexal masses.

Ovarian cancer is a primary malignancy of the ovary. Approximately 192000 new cases are discovered per year worldwide. Ovarian cancer is the third most common malignancy in women after cervical and breast cancer. Ovarian cancer is more common in older women, with a peak incidence at about 60 yrs of age. About 30% of ovarian neoplasms in postmenopausal women are malignant, whereas only about 7% of ovarian epithelial tumours in premenopausal patients are frankly malignant. Ovarian cancer is associated with low parity and infertility. Because parity is inversely related to the risk of ovarian cancer, having atleast one child is protective for the disease, with a risk reduction of 0.3 to 0.4%. Oral contraceptive use reduce the risk of epithelial ovarian cancer. Women who use OCP for 5 or more years reduce their relative risk to 0.5%. Most epithelial ovarian cancers are sporadic, but atleast 5-10% result from inherited susceptibility and are hereditary. Hereditary ovarian cancers, particularly those caused by BRCA 1 mutations occur in women approximately 10 years younger than those with non hereditary tumours. In the first 2 decades of life, almost 70% of ovarian tumours are of germ cell origin and one third of these are malignant. Metastatic tumours to the ovaries are most frequently from the breast and gastrointestinal tract. Survival rate of ovarian malignancy is very poor. Standard management of patients with tumour clinically localised to the ovary includes comprehensive surgical staging to guide subsequent need for further adjuvant treatment and to provide prognostic information. For patients with metastatic disease, numerous retrospective and prospective studies have shown that the extent of residual disease after radical surgical debulking is a significant predictor of both progression free and overall survival. More recently, intraperitoneal chemotherapy has shown significant survival benefits over standard intravenous chemotherapy in metastatic disseat has been optimally debulked at the time of initial surgical exploration, confirming the importance of aggressive surgical tumour resection at the time of initial diagnosis. Patients with malignant tumours should be referred to a gynaecological oncologist, as the quality of cytoreductive surgery and surgical staging/lymph node dissection are important prognostic factors in ovarian cancer. Furthermore, appropriate and timely referral to a gynaecological oncologist has been proven to increase survival in patients with ovarian cancer.

A womans risk at birth of having ovarian cancer at some point in her lifetime is 1% to 1.5% and that of dying from ovarian cancer is almost 0.5%.

The sensitivity was defined as the percentage of patients with malignant disease having a positive test result. The specificity was defined as the percentage with benign disease having a negative test result. The positive predictive value was defined as the percentage of patients with a positive test result having malignant disease and negative predictive value defined as the percentage of patients with a negative test result having benign disease.

The gynecological oncology MDT in Singleton Hospital currently uses RMI 1 based on NICE's recommendation. The MDT considers pelvic masses with an RMI 1 score < 25 as low risk, which should be managed locally, 25–250 as intermediate risk, which would be discussed at the MDT and managed locally if appropriate, and > 250 as high risk, which would require further investigation and immediate referral to a cancer center. Based on this study, a threshold of 250 has a sensitivity and specificity of 60% and 94%, respectively, for RMI 1. While noting that current evidence did not indicate the optimum cutoff to use for guiding management, NICE recommends a cutoff of 250 because it was thought that this would ensure access to specialist centers without overburdening them with benign disease and the associated additional costs.

The RMI 3 is a modified version of the RMI 1, which was proposed by Tingulstad et al. In their study they observed that sensitivity and specificity to malignancy were 71% and 92% respectively when a cut off of 200 was used.

This study demonstrates the ability of RMI to correctly identify benign and malignant adnexal masses. It shows the high specificity of the risk of malignancy index at an optimal cut off of 100. The specificity of RMI 3 was 92% in our study. High specificity is important because it reduces the number of surgical procedures performed for benign cases in tertiary gynecological oncology centres, therefore optimizing resources for patients with malignant pelvic masses. Using a cut off of 100, the preoperative RMI had sensitivity of 96%.

Conclusion

The RMI is a simple scoring system and has a high sensitivity and specificity for the detection

of malignant adnexal masses. Application of the RMI in clinical practice may provide a rational basis for speciduals to treat patients with adnexal masses before diagnostic surgery. It is simple, easy to use and cost effective. However its predictive accuracy was less for mucinous was compared to serious epithelial ovarian cancer. It should be noted that RMI is only a guide, therefore patients with a family history of ovarian and / or breast cancer and those with post medical history of breast and reproductive tract malignancy should be further evaluated even when their RMI score is low.

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