International Journal of Clinical Obstetrics and Gynaecology

ISSN (P): 2522-6614
ISSN (E): 2522-6622

www.gynaecologyjournal.com
2019; 3(1): 128-130
Received: 01-11-2018
Accepted: 05-12-2018

Sweta Kumari
Department of Obs and Gynae, LTMMC, Maharashtra, India

Shailesh Kore
Department of Obs and Gynae, LTMMC, Maharashtra, India

Ekta Jaiswal
Department of Obs and Gynae, Tulip Hospital, Sonepat, Haryana, India

Correspondence
Sweta Kumari
Department of Obs and Gynae, LTMMC, Maharashtra, India

Risk of malignancy index for pre-operative diagnosis of ovarian cancer

Sweta Kumari, Shailesh Kore and Ekta Jaiswal

DOI: https://doi.org/10.33545/gynae.2019.v3.i1c.21

Abstract
Objective: To determine clinical role of risk malignancy index to differentiate between benign and malignant ovarian masses.
Material and Methods: A prospective study was carried out in 40 women with ovarian mass in the Department of Gynecology, LTMMC, Maharashtra, India between February 2013 to October 2014. The profile of these patients was recorded in a predesigned proforma. Ultrasound, serum CA-125 level and menopausal scoring was done as a part of RMI calculation. Histopathology reports were later analyzed for final correlation with ultrasound findings, serum CA-125 level and menopausal status separately and RMI-1 and RMI-2 in combination.
Results: Both RMI-1 and RMI-2 have shown the ability of correctly identifying both benign and malignant ovarian mass with the arc under the curve in ROC 93.2% for RMI-1 and 90.99% for RMI-2. Both RMI-1 and RMI-2 value were significantly higher in malignant neoplasm than benign. RMI-1 had the highest sensitivity and specificity at the cut-off point 200. With the cut off value of >=200 used to diagnose malignant neoplasm, it had a sensitivity of 90.9%, specificity 94.4%,PPV 95.2% and NPV 89.5% in RMI-1 and sensitivity 90.9%, specificity 72.2%,PPV 80% and NPV 86.7% in RMI-2. Considering both RMI-1 and RMI-2 at the cut off value of 200, out of total 20 malignant cases, 2 cases of ovarian cancers were missed.
Conclusion: RMI is very useful in pre-operative diagnosis of ovarian malignancy. It overcomes the false positive result obtained while using a single parameter like serum CA-125 or USG alone.

Keywords: RMI; ovarian mass; CA-125

Introduction

Ovarian cancer is the second most common malignancy of the female genital tract after carcinoma of cervix. It accounts for 10-15% of total genital malignancies in India [1] and it kills more women every year than cancer of all other genital sites combined [2]. Hence, it is crucial to have a fair idea regarding the nature of mass - benign or malignant at the preoperative stage so that primary surgery can be optimally planned and undertaken. The problem of preoperative diagnosis of ovarian masses has not yet been completely solved [3] especially in resource limited settings such as India. This results in some patients having suboptimal oncoreductive surgery and others being under staged with attendant risk of under treatment [4].

Pre-operative assessment of an ovarian mass is generally done by bimanual pelvic examination, ultrasonography, Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET) and Tumour markers (CA-125, CA-15-3, CA-19-9).

A scoring method based on menopausal status, ultrasonographic examination and serum CA-125 yield much better results than the earlier mentioned individual parameters. Such a score "Risk of Malignancy Index" (RMI) is calculated with a simplified regression equation obtained from the product of menopausal status score (M), ultrasonographic score (U) and absolute value of serum CA-125 [5, 6].

RMI = U x M x Serum CA-125

Risk of Malignancy Index, originally developed by Jacobs *et al*. **Error! Bookmark not defined.** is known as RMI - 1 and that developed by Tingulstad *et al*. [6] with slight modification in score value of menopausal status and ultrasound score is RMI – 2.

Materials and Methods

This prospective study was conducted in the Department of Obstetrics and Gynecology, Lokmanya Tilak Municipal Medical College, Maharastra, from February 2013 to October 2014.

This study was approved by the Institutional Ethics Committee of Lokmanya Tilak Municipal Medical College (LTMMC). A total of 40 patients diagnosed with ovarian mass of size more than 6 cm including functional cysts and inflammatory masses admitted for laparatomy were included in the study. The data was collected after explaining the study protocol and informed written consent. The exclusion criteria in the study was ovarian masses less than 6 cm with clear cysts in reproductive age group, patient who already had histological diagnosis and patient not willing for surgical exploration. Ultrasound, serum CA-125 level and menopausal scoring was done as a part of RMI calculation.

RMI = U X M X Serum CA-125 level

Ultrasound scoring of the ovarian mass was based on one point for each of the following features:

1. Bilateral lesion
2. Multilocular cyst or septation
3. Evidence of solid areas
4. Evidence of metastasis
5. Presence of ascites

For RMI-1

USG Score U = 0 for ultrasound features of 0
U = 1 for ultrasound features of 1
U = 3 for ultrasound features of 2 to 5

For RMI-2

USG Score U = 1 for ultrasound features of 0 or 1
U = 4 for ultrasound features of 2 or more

For menstruating women score of 1 was given in both RMI-1 and RMI-2. But in post-menopausal women, score in RMI-1 was 3 and score in RMI-2 was 4.

Operative findings during laparotomy were obtained. Histopathology reports were later analyzed for final correlation with ultrasound findings, serum CA-125 level and menopausal status separately and RMI-1 and RMI-2 in combination.

Cases were managed according to institute protocol. All the collected data was transferred to predesigned proforma and data was analyzed using SPSS (version 12) and Excel 2010 software.

Results

In this prospective study of patients with ovarian mass, 40 patients were included. Following were the results found.

Menopausal Status

Among 40 patients, 67.5% (25/40 cases) had achieved menopause while 32.5% (15/40 cases) were menstruating.

Ultrasonography findings

All patients with ovarian mass were referred for sonographic evaluation.

Table 1: Ultrasonographic findings of ovarian mass

Findings	Frequency	Percent
Solid mass	23	57.5
Septation/ Loculations	20	50
Bilateral	18	45
Ascites	6	15
Metastasis	1	2.5

Table 2: Serum CA 125 level in individual ovarian neoplasm

Type of Malignancy	Mean (U/ml)	Range
Borderline serous carcinoma	102.3	0-204.6
Serous cystadenocarcinoma	540.8	258-896
Mucinous cystadenocarcinoma	219.5	38-580
Immature cystic teratoma	186	186
Granulosa cell tumour	191.7	160-214

Table 3: Serum CA-125 cut off for diagnosis of benign or malignant mass

CA 125 Level	Disease Status		p Value
	Malignant	Benign	
≥ 100 U/ml	17	0	<0.001
< 100 U/ml	5	18	

Risk Malignancy Index in diagnosis of malignant ovarian masses

RMI = U x M x Serum CA-125

Sensitivity, specificity, positive predictive value, negative predictive value and odds ratio were calculated for different RMI-1 and RMI-2 cut off points.

Table 4: Sensitivity, specificity, PPV, NPV and Odds ratio of RMI-1 at different cut off points

Cut off point RMI-1	Sensitivity (%)	Specificity (%)	PPV	NPV	Odds Ratio
150	83.3	90.9	88.2	86.9	50
200	94.4	90.9	89.5	95.2	170
250	94.4	81.8	80.9	94.7	76.5

Table 5: Sensitivity, specificity, PPV, NPV and Odds ratio of RMI-2 at different cut off points

Cut off point RMI-2	Sensitivity (%)	Specificity (%)	PPV	NPV	Odds Ratio
150	55.6	90.9	83.3	71.4	12.5
200	72.2	90.9	86.7	80	26
250	77.8	100	87.5	83.3	35

While comparing the RMI-1 and RMI-2 in differentiating non malignant and malignant ovarian tumors, RMI-1 had better diagnostic statistics (Sensitivity, Specificity, PPV and NPV).

Discussion

RMI, a simple scoring system consisting of ultrasound score, menopausal status and serum CA-125 level has been developed to correctly discriminate benign from malignant adnexal mass. This overcomes the false positive result obtained while using a single parameter serum CA-125 or USG alone, and also increases the sensitivity and specificity in the pre-operative diagnosis of ovarian mass.

Both RMI-1 and RMI-2 were calculated with formula-

RMI = Ultrasonographic score X Menopausal status X Absolute CA 125 level

In RMI – 1, the menopausal score for premenopausal status is one & postmenopausal status is three. The USG score is zero, one and three for no features, single feature and 2-5 features respectively.

In RMI – 2, the menopausal score for premenopausal status is one & postmenopausal status is four. The USG score is one for no or one features and and four for two or more features.

In the present study, both RMI-1 and RMI-2 have shown the ability of correctly identifying both benign and malignant ovarian mass with the area under the curve in ROC 93.2% for RMI-1 and 90.9% for RMI-2. Both RMI-1 and RMI-2 values were significantly higher in malignant neoplasm than benign.

RMI-1 had the highest sensitivity and specificity at a cut off point 200. With the cut off value of $\geq$ 200 used to diagnose malignant neoplasm, it had a sensitivity of 90.9 %, Specificity 94.4%, PPV 95.2% and NPV 89.5% in RMI -1 and sensitivity of 90.9 %, Specificity 72.2%, PPV 80% and NPV 86.7% in RMI-2.

Comparing RMI-1 and RMI-2 in differentiating benign and malignant ovarian mass

In the present study, RMI-1 was better than RMI-2 in diagnosing the malignant nature of the ovarian masses, with area under the curve 93.2% in RMI-1 and 90.9 % for RMI-2. At a cut-off value of 200, RMI-2 in the present study falsely diagnosed malignancy in 3 benign ovarian lesions in addition to those diagnosed by RMI-1. This is because, benign teratoma which is benign, accounted for half of the cases. Ultrasonographic features of these tumors had bilaterality, septations and solid components thereby mimicking malignancy and raising the RMI-2 value. At this cut off value, both RMI-1 and RMI-2 had a sensitivity of 90.9%. The other parameters were better in RMI-1 as compared to RMI-2. Thus, at a cut off value of 200, sensitivity of both RMI-1 and 2 were same (90.9%) which is in relatively better than previous studies undertaken by Jacobs *et al*. [5], Tingulstad *et at*. [6] and Asif *et al*. [7] who observed the sensitivity of 85.4%, 87% and 85% respectively.

Regarding specificity at the same value (200), RMI-1 was found to have better performance than RMI-2 (94.4% versus 72.2%) in the current study. This finding is not in agreement with the previous studies of Tingulstad *et al*. [6] and Morgante *et al*. [3] where performance of RMI-2 was observed to be better than RMI-1.

Conclusion

Risk of malignancy Index (RMI) is a simple, valuable, highly reliable index and is clinically applicable in pre-operative evaluation of ovarian masses. RMI-1 and RMI-2 are equally accurate in predicting malignancy in ovarian masses. RMI is very useful in pre-operative diagnosis of ovarian malignancy, which helps in appropriate management by counselling patient and patient companion regarding the possible diagnosis, treatment options and plans, preparing surgical team and timely referral to specialized oncological unit if need arises.

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