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ORIGINAL RESEARCH

Role of Risk of Malignancy Index 4 in evaluation of ovarian masses

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ABSTRACT

Objectives: To find the Risk of malignancy index 4 among women with ovarian masses and to evaluate its ability to discriminate benign mass from a malignant mass.

Methods: It is a prospective study including 30 random women with ovarian masses attending OPD and emergency of department of Obstetrics and gynaecology, Index Medical College and Hospital Indore. After obtaining informed consent from all patients, a full history was obtained and a general and gynaecology examination was performed.

Results: The p-value of RMI 4 for differentiating benign and malignant tumor for serous and mucinous histology was less than 0.05 which indicated significant correlation. But for other histologies, the p-value was more than 0.05 which indicated non-significant correlation.

Conclusion: RMI 4 is a reliable tool for differentiating benign and malignant tumors. It is a simple, reliable and applicable method in the primary evaluation of patients with ovarian masses.

Keywords: RMI, Ovarian mass, Gynaecology

INTRODUCTION

Pelvic mass is one of the most common clinical presentations, representing a number of benign and malignant conditions and it is essential to differentiate them for the accurate management of the patients (1).

Common pelvic masses and their differential diagnosis are -Ovarian (ovarian neoplasm, ovarian cyst, endometriosis, Tubo-ovarian mass), Uterine (Myomas), Gastrointestinal (diverticulitis, appendicular mass), Tubal pathology (ectopic pregnancy, hydrosalpinx/pyosalpinx, tubal neoplasms) and Genitourinary (pelvic kidney). (2) Evaluation of ovarian masses is done by Clinical examination, Imaging (Ultrasonography, Doppler scan, CT/MRI/PET scan), Tumor markers (CA 125), Combined methods (RMI, ADNEX method, IOTA simple rules, LR2 method), and Histopathology (3).

Risk of malignancy index (RMI) is a combined parameter which is simple, preclinical, highly sensitive and more specific. The main advantage is that it is a simple scoring system that can be applied directly into clinical practice without the introduction of expensive or complicated methods (such as CT scan, MRI and whole-body emission tomography).(4) Four versions of RMI have been proposed i.e., RMI 1, RMI 2, RMI 3 and RMI 4. RMI 4 is the recent version that also includes tumor size and is considered to be more reliable as compared to previous versions.(3,5)

The aim and objectives of the study are to find the Risk of malignancy index 4 among women with ovarian masses and to evaluate its ability to discriminate benign mass from a malignant mass.

METHODS

It is a prospective study including 30 random women with ovarian masses attending OPD and emergency of department of Obstetrics and gynaecology, Index Medical College and Hospital Indore. This study was conducted after taking permission from thesis and ethical committee of our institution. After obtaining informed consent from all patients, a full history was obtained and a general and gynaecology examination was performed. Subjects then underwent a transvaginal or transabdominal ultrasound in the department of Radiodiagnosis, Index Medical College and Hospital Indore. Patient's preoperative ultrasound findings, serum CA125 levels and menopausal status were noted.

Women with ovarian masses attending OPD or emergency, and willing for FNAC/histopathological examination/surgical procedure were included in this study. Women with functional cyst <5 cm, subject with evidence of hepatic, peritoneal metastasis or lung metastasis were excluded.

Based on data obtained, RMI 4 was calculated. Subjects were then posted for surgical exploration/FNAC. Specimen of ovarian mass were sent for histopathological examination in the department of pathology, Index Medical College and Hospital Indore. Histopathological results were analyzed for correlation with RMI 4.

RMI 4 = U (ultrasound score)×M (menopausal score)×S (Tumor size in cms)×CA 125.

- A score is assigned for the following ultrasound features, which are suggestive of malignancy:

1. Presence of a multilocular cystic lesion
2. Solid areas
3. Bilateral lesions
4. Ascites
5. Intra-abdominal metastasis

Each receives a score of one point.

A total ultrasound score of 0 or 1 is U=1, and a score of >2 is U=4.

- Premenopausal status is M=1 and postmenopausal status is M=4.
- A tumor size (single greatest diameter) of <7 cm is S=1 and >7 cm is S=2.
- The serum level of CA125 is applied directly to the calculation.(2)

STATISTICAL ANALYSIS

The 't'-test for the mean and the Chi-square test was used to compare the demographic, biochemical and ultrasonographic data of subjects with benign and malignant ovarian masses. The SPSS software was used in performance of statistical analysis. In this study, the variable was RMI 4 and outcome was malignant nature of ovarian mass.

RESULTS

Table 1: Distribution of subjects by age (n=30).

Age group (in years)	Benign (n=19)	Malignant (n=11)	Total (n=30)	P-value
<30	5(50)	5(50)	10 (100)	0.311
30-44	9(81.8)	2 (18.18)	11 (100)	
45-54	4 (66.66)	2 (33.33)	6 (100)	
>55	1 (33.33)	2 (66.66)	3 (100)	

Total	19 (63.33)	11 (36.66)	(100)	

The p-value was 0.311 (>0.05) which indicated that there was no significant correlation between occurrence of benign and malignant disease and age in the present study. This could be explained by the relatively younger age of subjects with malignant disease.

Table 2: Predictive value of menopausal score

Menopausal status	Benign (n=19)	Malignant (n=11)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Premenopausal (score=1)	14	7	36.36	73.68	44.44	66.67
Postmenopausal (score=4)	5	4				

There was no statistically significant correlation between menopausal status and occurrence of benign and malignant disease in the present study (p-0.563). This showed that menopausal status was not a predictor of ovarian malignancy. The sensitivity of menopausal score in diagnosing malignancy was 36.36% and specificity was 73.68%. The positive predictive value was 44.44% and negative predictive value was 66.67% in the study.

Table 3: Distribution of subjects by CA 125.

Age group (in years)	Benign (n=19)	Malignant (n=11)	Total (n=30)	P-value
<35	11 (91.66)	1 (8.33)	12(40)	0.09
>35	8 (44.44)	10 (55.55)	18(60)	
Mean	56.09	352.64		
SD	68.93	433.15		
Median	26.80	168.00		
Minimum	8.45	9.90		
Maximum	302.90	14447.70		

The relation between occurrence of benign and malignant disease with CA 125 was not statistically significant in the study. This could be explained by the fact that CA 125 could be raised in other inflammatory conditions of the abdomen especially in the premenopausal females who formed the bulk in present study.

Table 4: Predictive value of CA 125

CA 125 (u/mL)	Benign (n=19)	Malignant (n=11)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
<35	11	1	90.91	57.89	55.56	91.67
>35	8	10				

The sensitivity of CA 125 in diagnosing malignancy was 90.91% and specificity was 57.89 %. The positive predictive value was 55.56% and negative predictive value was 91.67% in the present study.

Table 5: Predictive value of ultrasonography score.

USG score	Benign (n=19)	Malignant (n=11)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
1	10	1	90.91	52.63	52.63	90.91
4	9	10				

As the p-value in this case was 0.017 (<0.05), the relation between occurrence of benign and malignant disease with ultrasonography score was statistically significant. The sensitivity of USG score in predicting malignancy was 90.91% and specificity was 52.63%. The positive predictive value was 52.63% and negative predictive value was 90.91% in the present study.

Table 6: Predictive value of Tumor size

Tumor size (in Cms)	Benign (n=19)	Malignant (n=11)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
< 7	0	2	81.82	0.00	32.14	0.00
> =7	19	9				

As the p-value was 0.05, so there was statistically significant correlation between occurrence of benign and malignant disease and tumor size in the study. The sensitivity of tumor size in predicting malignancy was 81.82%. Specificity could not be defined in this study. The positive predictive value was 32.14%. The negative predictive value could not be defined as there was no benign tumor of size less than 7 cm.

Table 7: Predictive value of RMI 4

RMI 4	Benign (n=19)	Malignant (n=11)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
< 450	17	3	72.73	89.47	80.00	85.00
> 450	2	8				

The value of RMI 4 was less than 450 in 17 (85%) subjects with benign disease and 3 (15%) subjects with malignant disease. The value was more than 450 in 2 (20%) subjects with benign disease and 8 (80%) subjects with malignant disease. The p-value for RMI 4 in the study was 0.001 which was highly significant. This concluded that the RMI 4 is a reliable tool in differentiating benign and malignant ovarian tumors. The sensitivity of RMI 4 in predicting malignancy was 72.73% and specificity was 89.47%.

Table 8: RMI 4 Versus histologic type

	SEROUS(n=9)			MUCINOUS (n=6)			OTHERS (n=15)		
RMI 4	Benign	Malignant	Border line	Benign	Malignant	Border line	Benign	Malignant	Border line
<450	7	1	-	3	0	-	7	2	-
>450	0	1	-	0	3	-	2	4	-
	P-value=0.047*			P-value=0.014*			P-value=0.085		

The p-value of RMI 4 for differentiating benign and malignant tumor for serous and mucinous histology was less than 0.05 which indicated significant correlation. But for other histologies, the p-value was more than 0.05 which indicated non-significant correlation.

DISCUSSION

CA125 was first described by Bast et al (6) and found elevated levels in 80% of epithelial ovarian cancers. They stated that 35 IU/mL was a threshold value for CA125 in their following study (7) and afterwards many studies related CA125 were made in preoperative diagnosis of an adnexal mass.

The sensitivity of CA 125 in diagnosing malignancy was 90.91% and specificity was 57.89 %. The positive predictive value was 55.56% and negative predictive value was 91.67% in the present study. Specificity and PPV for M were higher than the values reported in the literature (8-11).

In a systematic review of 109 studies including 21750 women with adnexal masses consisted of 83 different prediction models. RMI was the best predictor and when 200 were used as the cutoff level, the pooled estimate for sensitivity was 78% for a specificity of 87% (12). In our study RMI was also best predictor for discriminating between benign and malignant in women with ovarian masses preoperatively.

CONCLUSION

RMI 4 is a reliable tool for differentiating benign and malignant tumors. It is a simple, reliable and applicable method in the primary evaluation of patients with ovarian masses.

REFERENCES

1. ACOG practice bulletin. Management of adnexalmasses. Obstet Gynecol. 2007;110:201-14.
2. Scully RE, Sobin LH. Histological typing of ovariantumours. Springer Sci Business Media; 1999.
3. Taylor HC. Malignant and semi-malignant tumors of the ovary. Obstet Gynecol. 1929;48:204-30.
4. Gwinn ML, Lee NC, Rhodes PH, Layde PM, RubinGL. Pregnancy, breast feeding, and oral contraceptives and the risk of epithelial ovarian cancer. J Clin Epidemiol. 1990;43:559-68.
5. Zorn KK, Tian C, McGuire WP, Hoskins WJ,Markman M, Muggia FM, et al. The prognostic value of pretreatment CA 125 in patients with advanced ovarian carcinoma. Cancer.2009;115(5):1028-35.
6. Bast RC Jr, Feeney M, Lazarus H, et al. Reactivity of a monoclonal antibody with human ovarian carcinoma. J Clin Invest 1981; 68: 1331-7.
7. Klug TL, Bast RC Jr, Niloff JM, et al. Monoclonal antibody immunoradiometric assay for an antigenic determinant (CA125) associated with human epithelial ovarian carcinomas. Cancer Res. 1984; 44: 1048-53.
8. Jacobs I, Oram D, Fairbanks J, et al. A risk of malignancy index incorporating CA 125, ultrasound and menopausal status for the accurate preoperative diagnosis of ovarian cancer. Br J Obstet Gynaecol. 1990; 97: 922-9.
9. Tingulstad S, Hagen B, Skjeldestad FE, et al. The riskof- malignancy index to evaluate potential ovarian cancers in local hospitals. Obstet Gynecol.1999; 93: 448-52.
10. Manjunath AP, Pratapkumar, Sujatha K, Vani R. Comparison of three risk of malignancy indices in evaluation of pelvic masses. Gynecol Oncol.2001; 81: 225-9.
11. Ma S, Shen K, Lang J. A risk of malignancy index in preoperative diagnosis of ovarian cancer. Chin Med J. 2003;116: 396-9.
12. Geomini P, Kruitwagen R, Bremer GL, et al. The accuracy of risk scores in predicting ovarian malignancy: a systematic review. Obstet Gynecol.2009: 113: 384-94.