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Pre-Operative Evaluation of Ovarian Tumours by Risk of Malignancy Index 2 at a Tertiary Care Centre of Rajasthan

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Abstract: A pelvic mass is one of the most frequent indication for referral to a higher centre. The accurate diagnosis of an adnexal mass is a challenge for the gynaecologists. RMI 2 is a multiparametric index developed to discriminate benign and malignant tumours. The purpose of the study was to evaluate the ability of RMI 2 to discriminate between benign and malignant ovarian tumours at a tertiary care centre of Jaipur. This was a prospective observational study.180 patients with ovarian tumours admitted for laparotomy was included in the study after obtaining written informed consent. Menopausal status, USG score and Serum levels of CA 125 measured for all and RMI 2 was calculated. Diagnostic ability of RMI was evaluated. On univariate analysis, there was significant difference in patients with benign and malignant tumour on the basis of menopausal status, USG score & CA 125 levels. At a cut off of 200, RMI 2 had a sensitivity of 80% (63.06 - 91.56), Specificity of 97.24 (93.09 - 99.24), positive predictive value of 87.50%, negative predictive value of 95.27% and diagnostic accuracy of 93.89%. RMI 2 is a simple mathematical formula used to discriminate benign and malignant ovarian tumours. It will help in selective referral of patients to higher centres.
Keywords: pelvic mass, malignant tumours, ovarian tumours.

INTRODUCTION

A pelvic mass is one of the most frequent indication for referral to specialist gynecologists. Often these pelvic masses are malignant and require surgical management. The accurate diagnosis of an adnexal mass is a challenge for the gynaecologists, because of its bizarre and atypical behavior [1, 2].

Preoperative diagnostic procedures that are able to distinguish whether an ovarian neoplasm is malignant or benign could be useful in planning optimized treatment. Several diagnostic methods for pelvic masses have been reported, such as abdominal and transvaginal ultrasonography, three-dimensional ultrasound, colour Doppler ultrasonography and tumor markers [3, 4]. However, none of these methods used individually has shown significantly better performance in detecting malignant tumors. Leelahakorn *et al.*, [5] in their study observed sensitivity and specificity of ultrasonography in diagnosis of malignant condition as 62% and 73%, respectively. Elevation of serum CA 125 concentrations is documented in 85% of epithelial ovarian cancers [6, 5]. Benjapibal *et al.*, [6] in their study observed a sensitivity of 83.1% and specificity of 39.3% at the cut-off level of 35 U/ml for serum CA 125.

Jacob *et al.*, [7] originally developed the RMI based on ultrasonographic findings, menopausal status, and serum levels of CA 125. RMI 1, at a cut-off level of 200 to indicate malignancy, had a sensitivity and specificity of 85.4% and 96.9%, respectively. Tingulstad *et al.*, [8] developed RMI 2.The RMI 2 gave sensitivity of 80%, specificity of 92% and positive predictive value (PPV) of 83%. The purpose of the study was to evaluate the ability of RMI 2 to discriminate between benign and malignant ovarian tumours at a tertiary care centre of Jaipur.

MATERIALS AND METHODS

This was a prospective observational study done in the Department of Obstetrics and Gynaecology, S.M.S, Medical College, Jaipur. 180 patients with ovarian tumours admitted for laparotomy were included in the study after obtaining written informed consent.

All patients were evaluated by detail history and examination. Ultrasound evaluation by either a 3.75-MHz abdominal transducer or a 7.5-MHz transvaginal probe was done. The presence of multilocularity, solidity, bilaterality, ascites and presence of metastasis scored 1 point for each. USG score was assigned as U = 1 if 0 or 1 criteria fulfilled and U = 4 if 2 or more criteria are fulfilled.

Postmenopausal status is defined as amenorrhea of more than one year or age older than 50 years in women who had a hysterectomy. Women who did not meet these criteria were classified as premenopausal. Menopausal score was assigned as M = 1 for premenopausal and M = 4 if postmenopausal. Serum CA 125 levels were also measured for eac patient preoperatively. RMI 2 was calculated for all patients using the formula given by Tingulstad *et al.*, 1996 as

RMI 2 = U x M x absolute value of serum CA 125.

The chi-square test was used to test differences in distribution of age, menopausal status and ultrasonographic score. A p value <0.05 was considered to be statistically significant.

The sensitivity, specificity, positive predictive and negative predictive value with reference to the presence of a benign and malignant ovarian tumour was calculated. The histopathological diagnosis was considered as the gold standard for defining the outcomes.

RESULTS

Mean age of the patients with benign tumour (33.54±14.39 years) was significantly lower than mean age of the patients with malignant tumours (44.34±13.89 years) (p value 0.0001)

Table-1 shows distribution of the patients according to menopausal status, USG score and serum CA 125 levels. 42.9% patients with malignant tumours were postmenopausal in contrast to 15.9% women with benign tumours. The difference in the menopausal status and nature of the ovarian tumours was statistically significant (p value 0.0004). 82.9 % patients with malignant tumours had a USG score 4 in contrasts to 5.6% patients with benign tumours. The difference was statistically significant (p .0000). Out of 145 women with benign tumours 91.7% had serum CA 125 levels less than 35U/ml while 77.2% patients with malignant tumours had serum level of Ca 125 more than 35U/ml. The difference in S. levels of CA 125 was statistically significant in benign and malignant tumours (P -0.000)

Evaluation of diagnostic ability of RMI 2 has been shown in table 2. Out of 32 patients with RMI score >200, 87.5 were malignant and out of 148 patient with RMI score <200, 95.3% had benign disease. Out of 35 patients with malignant tumours, 80% were predicted to be malignant on RMI 2 i.e. true positive. Similarly out of 145 benign tumours, 97.2% were predicted to be benign on RMI 2 i.e. true negative. At a cut off of 200, RMI 2 had a sensitivity of 80% (63.06 - 91.56), Specificity of 97.24 (93.09 - 99.24), positive predictive value of 87.50%, negative predictive value of 95.27% and diagnostic accuracy of 93.89%.

Diagnostic ability of different parameters (RMI2, menopausal score, Usg score and CA 125) to differentiate between benign and malignant tumours has been shown in table 3. Sensitivity of RMI 2 was 80%, specificity 97.24%, positive predictive value of 87.50%, negative predictive value of 95.27% and diagnostic accuracy of 93.89%. Menopausal score when used alone had a sensitivity of 42.86%, specificity 84.14%, positive predictive value of 39.47%, and negative predictive value of 85.92% and diagnostic accuracy of 76.11%. USG score when used individually had a sensitivity of 82.86%, specificity 94.48%, positive predictive value of 78.38%, and negative predictive value of 95.80% and diagnostic accuracy of 92.22%. Sensitivity, specificity, PPV, NPV and diagnostic accuracy of S. CA 125 was 77.14%, 91.72%, 69.23%, 94.33% and 88.89% respectively.

Table-1: Distribution of patients by menopausal status, serum CA125 levels and ultrasound score

Variables	Benign (n = 145)		Malignant (n = 35)		p value
	No.	%	No.	%	
Menopausal status					
Premenopausal	122	84.1	20	57.1	0.0004
Postmenopausal	23	15.9	15	42.9	
USG score					
1	137	94.4	6	17.1	<0.0000
4	8	5.6	29	82.9	
CA125					
<35	133	91.7	8	22.8	0.000
≥35	12	8.3	27	77.2	

Table-2a: Evaluation of RMI 2

Variables	Benign (n = 145)		Malignant (n = 35)		p value
	No.	%	No.	%	
RMI 2					
<200	141	97.2	7	20.0	0.000
>200	4	2.8	28	80.0	

Table-2b: Performance of RMI 2

Statistics	Formula	Value	95% CI
Sensitivity	TP/TP+FN	80.00	63.06 - 91.56
Specificity	TN/TN+FP	97.24	93.09 - 99.24
Positive Likelihood Ratio	Sensitivity/1-Specificity	29.00	10.88 - 77.31
Negative Likelihood Ratio	1-Sensitivity/Specificity	0.21	0.11 – 0.40
PPV	TP/TP+FP	87.50	72.42 - 94.91
NPV	TN/FN+TN	95.27	91.21 -97.51
Accuracy	TP+TN/TP+FP+FN+TN	93.89	89.33 - 96.91

Table-3: Diagnostic ability of RMI 2, Menopausal score, USG score, S. CA 125 levels

	RMI 2	Menopausal score	USG score	S CA 125
Sensitivity	80.00 63.06 - 91.56	42.86 26.32 - 60.65	82.86 66.35 - 93.44	77.14 59.86 - 89.58
Specificity	97.24 93.09 - 99.24	84.14 77.16 - 89.67	94.48 89.42 - 97.59	91.72 85.99 - 95.65
Positive Likelihood Ratio	29.00 10.88 - 77.31	2.70 1.58 - 4.62	15.02 7.53 – 29.95	9.32 5.27 - 16.50
Negative Likelihood Ratio	0.21 0.11 – 0.40	0.68 0.51 – 0.91	0.18 0.09 – 0.38	0.25 0.14 - 0.46
PPV	87.50 72.42 - 94.91	39.47 27.63 - 52.70	78.38 64.51 - 87.85	69.23 55.97 - 79.93
NPV	95.27 91.21 -97.51	85.92 81.95 - 89.13	95.80 91.67 - 97.93	94.33 90.03 - 96.84
Accuracy	93.89 89.33 - 96.91	76.11 69.20 - 82.14	92.22 87.29 - 95.68	88.89 83.36 - 93.08

DISCUSSION

The prevalence of malignancy in our study was 19.4% which was lower than that reported in previous studies [9, 10]. On univariate analysis there was significant difference in benign and malignat tumours in relation with menopausal score (p-), USG score (p-) and S CA 125 levels (p-) Our results are in accordance with that observed by [10-13].

This study was done to evaluate RMI 2 in discriminating benign from malignant ovarian tumours. At a cut off value of 200, RMI 2 had a sensitivity of 80% (63.06 - 91.56), specificity of 97.24 (93.09 - 99.24), positive predictive value of 87.50%, negative predictive value of 95.27% and diagnostic accuracy of 93.89%. The sensitivity of RMI 2 in our study was lower than that reported by Obeidat *et al*., [14], Y Yamimoto *et al*., [12] and Van Den Akkar *et al*., [15] and higher than that reported by Manjunath *et al*., [16], Ulusoy *et al*., [9], M K Zarchi *et al*., [17], Javdekar R [13], S K Dora *et al*., [18].

Sensitivity of Menopausal status, USG score and S CA 125 levels in our study was 42.86%, 82.86% and 77.14% respectively. Our results were comparable with the results observed by Javedkar *et al*., [13]. G.O Abdilrahman Jr *et al*., [19] in their study observed that the sensitivity and specificity of S CA 125 at 35 U/ml was 76% and 67% respectively. RMI 2 was more accurate in discriminating benign tumour from malignant tumours than any individual criteria. False positive rate of RMI 2 was only 2.8% which was much lower than 15.9% of Menopausal status, 5.6% of USG and 8.3% for S. CA 125 levels. Serum levels of CA 125 has been found to be raised in various benign conditions also like endometriosis, fibroid uterus, benign ovarian cysts and pelvic infections.

In conclusion, RMI is a simple mathematical formula based on inexpensive tests. Every centre should be encouraged to use it to discriminate benign and malignant ovarian tumours. It will help in selective referral of patients to higher centres.

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