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Research Article

Risk of malignancy index in assessment of pelvic mass

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Abstract

Objectives: The aim of study was to evaluate the use of risk of malignancy index in differentiating benign and malignant ovarian tumours.
Materials and methods: 90 women with adnexal mass were included in study. Risk of malignancy index calculated by incorporating ultrasound score, menopausal status and CA 125 level. Sensitivity, specificity, positive predictive value, and negative predictive value were calculated for RMI at different cut off levels in predicting ovarian cancer.
Observations: RMI at cut off level 200 seemed to perform better than the individual parameters used separately. The Sensitivity, specificity, positive predictive value, and negative predictive value of RMI at cut off 200 were 84, 89, 93 and 71% respectively.
Conclusion: RMI is a simple, easily applicable scoring system which helps in differentiating benign from malignant ovarian masses pre operatively and aids in timely referral to tertiary centre.
Keywords: risk of malignancy index, ovarian cancer, CA 125 level

1. Introduction

Ovarian cancer is one of the leading cause of mortality due to female genital tract malignancy.[1] Ovarian cancer has emerged as one of the most common malignancy affecting Indian women. The annual percentage of increase in age standardized incidence rates ranged from 0.7% to 2.4%. [2] Gynaecological cancers have increased in India and are estimated to be around 182,602 by the year 2020 constituting about 30% of the total cancers among women in India. Ovarian cancer being contributing about 19.8% of the total cases.[3] There are no established population-based screening programmes for the disease and few specific symptoms and signs of ovarian cancer. Consequently the majority of women present with advanced disease with poor prognosis. Survival in all cases at 1 year is 55% and at 5 years is 29%. Median survival is 14 months.[1] The Risk of Malignancy Index (RMI) developed by Jacobs *et al* is an objective tool based on menopausal status, ultrasound characteristics, and serum CA125 levels; it provides an algorithm that produces quantitative data for the identification of patients with high risk ovarian masses and subsequent referral to cancer center.[4]

We have done the study to evaluate performance of individual parameters as well as ability of Risk of Malignancy Index (RMI) to differentiate benign and malignant tumours.

Main objective of present study was to know the performance of Risk of Malignancy Index in differentiating benign from malignant tumours.

2. Methods

It is a retrospective analysis of 90 women admitted in the Department of Obstetrics and Gynaecology of K.S. Hegde Medical Academy, mangalore for a period of one year for surgical exploration of pelvic masses. The serum CA125 level, the ultrasound findings and menopausal status were noted. Serum CA 125 samples were assayed by radioimmunoassay. The ultrasound examination was performed using a 3.75-M Hz abdominal convex transducer (TOSHIBA).

A score was assigned for for each of the following ultrasound features suggestive of malignancy; presence of multilocular cystic lesion, solid areas, bilateral lesions, ascites and intra-abdominal metastasis. Each feature is given a score of one and total ultrasound score (U) was calculated for each patient. Post menopausal status was defined as more than one year of amenorrhea or an age of more than 40 years in women who had a hysterectomy. All other women were considered premenopausal. In women who underwent laparotomy, the specimen sent was for histopathological analysis. The histopathological diagnosis was considered gold standard in diagnosis of tumour. (FIGO Staging).

Based on data obtained, RMI was calculated for each patient along with the sensitivity, specificity, positive predictive value and negative predictive values.

RMI calculated by the equation, RMI= U×M×CA 125. (Jacobs *et al*, 1990)

Where, U= ultrasound score.

Total ultrasound score of 0 gave U=0, a score of 1 gave U=1, and a total score of ≥2 gave U=3;

M for menopausal status. Premenapausal status gave M=1, postmenapausal status gave M=3;

The serum CA 125 levels directly applied to the calculation.

The statistical analysis was performed using the statistical package for social sciences (SPSS Inc) version 5.0. the X2 test was used to test differences in distribution of age, ultrasound score and menopausal status.

Sensitivity was defined as the percentage of patients with malignant disease having a positive test result.

Specificity was defined as the percentage of patients with malignant disease having a negative test result.

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

3. Observations

The histological examination of the surgical specimens of 90 patients revealed malignancy in 53 cases (59%), benign in 29(32%) and borderline in 8(9%) of cases. Out of 53 cases of ovarian cancer, 4 at FIGO stage 1(7.55%), 10 at stage II (18.87%), 22 at stage III (41.51%), and 17 at stage IV (32.07%). Benign tumours included serous cystadenoma (n=9), mucinous cystadenoma (n=7), dermoid cyst (n=6), thecoma(n=2), papillary serous cystadenofibroma(n=2), simple serous cyst(n=2) and haemorrhagic cyst(n=1). We had 8 borderline cases and they were excluded from statistical analysis. Mean age of women with benign tumours was 48.83±15.01 years, and that for malignant tumours was 57.8±42.96 years.

Table 1: Distribution of the diagnosis and stages in patients with pelvic mass

Diagnosis	Number (%)
Ovarian cancer	
Stage 1	4
Stage 11	10
Stage 111	22
Stage 1V	17
Total malignant cases	53(58.9%)
Serous cystadenoma	37
Mucinous cystadenoma	7
Endometriod carcinoma	3
Clear cell carcinoma	2
Malignant Brenner tumour	1
Dysgerminoma	1
Mucinous cystadenocarcinoma from mature teratoma	1
Krukenberg	1
Tumours of low malignant potential	8(8.9%)
Total benign tumours	29(32.2%)

In univariate analysis a significant linear trend of malignancy was found by increasing age and increasing ultrasound score. Malignancy was found more in postmenapausal patients (77%) compared to premenapausal patients (23%). The mean serum level of CA125 was significantly higher among women with malignancy when compared with women with benign tumours (2142.58U/ml Vs 19.18U/ml).

Table 2: Distribution of Age, menopausal status, ultrasound score and serum CA125 levels between Benign and Malignant tumours

Variable	Malignant	Benign	Test	P value
	N=53	N=29		
Age (years)				
<20	1(2%)	0(0%)	x^2(11.56)	0.021
21-30	0(0%)	3(10%)		
31-40	3(6%)	6(21%)		
41-50	13(25%)	7(24%)		
>50	36(80%)	13(45%)		
Menopausal status				
Premenopausal	12(23%)	15(52%)	x^2(7.17)	0.007
postmenopausal	41(77%)	14(48%)		
Ultrasound score				
0	0(0%)	0(0%)	x^2(7.86)	0.007
1	5(9%)	10(35%)		
2-5	48(91%)	19(66%)		
CA 125(iu/ml)				
Mean	2142.58	19.18	U test	
Minimum	3	5		
Maximum	12246	106		
Standard deviation	3046.94	20.05		

Table 3: Sensitivity, specificity, positive predictive value, negative predictive values of serum CA 125 level, Ultrasound score and menopausal status in the diagnosis of malignant pelvic mass

	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
CA 125(iu/ml)				
10	98.11	27.59	71.23	88.89
35	80.02	93.10	95.65	75.00
50	81.13	96.55	97.73	73.68
150	75.47	100	100	69.05
USG Score				
1	7.55	65.57	28.57	27.94
3	90.57	34.48	71.64	66.67
Menapausal status				
postmenapause	77.36	62.07	78.55	60.00

Table 4: Performance of RMI at various cut off levels

RMI values	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
50	94	51	78	83
100	90	68	84	80
150	81	70	91	70
200	84	89	93	71
250	93	71	81	89

The performance level of CA 125 level at 35u/ml was a sensitivity of 80.02% and a specificity of 93.10%. The sensitivity and specificity of ultrasound scores at three and above were 90.57% and 34.48% respectively. The performance obtained for the risk of malignancy at the cutoff point 200 was a sensitivity of 84% and specificity of 89%. When individual parameters were compared CA 125 levels performed better than ultrasound score and menopausal status. The best performance was RMI at a cut off level of 200.

4. Discussion

In women with ovarian mass, RMI does help in differentiating benign and malignant ovarian mass. Performance of RMI at cut off value 200 was better than any other parameter taken independently. RM I had better sensitivity compared to CA 125 levels. Study done by Jacobs *et al* showed a sensitivity of 73% and a specificity of 91 % at a cut off level 200.[4] In a study done by Manjunath and co workers, where the comparison between the three risk of malignancy indices were done on 152 patients found no significant differences between them at cut off level 200. However, in identifying malignancy, they found RMI had better performance than any other individual parameter.[5]

In a cross sectional study on 158 patients, it was shown that RMI at a cut off 200 had sensitivity 73% and specificity 86%.[6] Study by Ulsoy and co workers on 296 women concluded RMI identified malignant cases more accurately than any other individual criterion in diagnosing ovarian cancer.[7] Terzic M and co-workers in their study on 81 patients Sensitivity of RMI was 83.33%, specificity was 94.12%, positive predictive value was 89.29% and negative predictive value was 90.57% with cut off value of at 200.[8] In a retrospective study conducted in 209 women with pelvic masses, RMI was able to discriminate between benign and malignant tumours.[9]

The various modalities available in differentiating benign and malignant ovarian tumours include trans abdominal ultrasound, trans vaginal ultrasound, transvaginal colour Doppler, various tumour markers, PET/CT/MRI. No individual modality has proven the best in differentiating benign from malignant ovarian tumours.[10,11,12,13,14]

RMI remains mainstay of investigation in a woman with suspected ovarian mass and provides likelihood for referral to a multidisciplinary team specialised in its management.[1] RMI seems to be simple, easily applicable and available method particularly in primary evaluation of ovarian tumours as shown in our study also.

5. Conclusion

Risk of malignancy index is an appropriate method which identifies the probability of malignancy in patients with pelvic mass. It can be applied directly by knowing CA 125 levels, menopausal status and ultrasound characteristics and helps in pre operative assessment of adnexal mass and referring patients to gynaecological oncology centre for appropriate surgical intervention.

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