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Original Research Article

Comparison of efficiency between RMI1 and RMI2 in diagnosing ovarian malignancy

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ABSTRACT

Background: This study was conducted in department of obstetrics and gynaecology, to know the efficiency of risk of malignancy index (RMI) to differentiate a malignant from a benign tumor and to compare the efficiency of risk of malignancy index 1 and 2 (RMI1 and RMI2). The study was conducted from June 2012 to August 2013 in women who got admitted with adnexal tumor.

Methods: It was a prospective study. A proforma was designed for each patient which included, name, age, complaints, menopausal status, parity, past and family history and associated medical condition were asked. Individual parameters namely ultrasound score, CA125 and menopausal status and risk of malignancy index was calculated and compared with final histopathological diagnosis and sensitivity specificity and positive predictive value was calculated for each.

Results: : The sensitivity of RMI1 is 87.95%, specificity is 75%, positive predictive value is 94.8%, negative predictive value is 54.54%, percentage of false negative is 12.04% and percentage of false positive is 25%. The sensitivity of RMI2 is 86.74%, specificity is 81.25%, positive predictive value is 96%, negative predictive value is 54.16%, percentage of false negative is 13.25% and percentage of false positive is 18.75%.

Conclusions: The efficiency of RMI was definitely better than individual parameters and efficiency of RMI 1 and RMI2 are similar.

Keywords: CA125, Menopausal status, Ovarian malignancy, Risk of malignancy index, Ultrasound score

INTRODUCTION

Ovarian malignancy is one of the leading cause of death due to gynaecological malignancies.¹ They are asymptomatic in most of the cases and more than half have advanced disease at the time of diagnosis.² The incidence of malignancy increases with age and women with post menopausal status have thus increased risk of malignancy.

Therefore, preoperative knowledge of the nature of the adnexal mass is necessary so that optimal surgery can be planned at the time of initial treatment. The challenge for

general gynaecologists has been how to differentiate a benign adnexal mass from a malignant one so that an appropriate referral can be made preoperatively. The risk of malignancy index (RMI) has been shown to be of importance at primary health care centres and general gynaecologists so that a proper decision can be made regarding referral and treatment.^{3,4}

The objective of this study was to assess the ability of individual parameters namely menopausal status, ultrasound, CA125 and tumor size in pre operative evaluation of adnexal masses, to discriminate a benign from a malignant tumor. To assess the ability of risk of

malignancy indices RMI1 and RMI2 based on CA125, ultrasound findings and menopausal status, to discriminate benign from malignant adnexal masses. To compare the sensitivity, specificity and positive predictive value of RMI1 and RMI2 and of individual parameters.

There is no appropriate single investigation either serological or radiological preoperative method for differentiating benign from malignant ovarian tumor. Ultrasound findings, CA125 serum levels and menopausal status have been tested in isolation as diagnostic methods. The evaluation of three methods in association with each other can improve the diagnostic performance.⁵ The treatment efficiencies in patients with ovarian cancers can be increased by standardization of preoperative evaluation. Jacobs has introduced risk of malignancy index in 1990 and was the first diagnostic model that combined demographic ultrasonographic and biochemical parameters for investigating patients with adnexal masses. RMI was modified by Tingulstad for the first time in 1996 (RMI2) and in 1999 (RMI3). These three were assessed in many prospective and retrospective clinical studies.

METHODS

Women admitted to Karnataka Institute of Medical Sciences, Hubli with adnexal mass were chosen for the study. The study period was from June 2012 to August 2013. 100 women with adnexal masses met the inclusion criteria, out of this there was one drop out as patient was given neoadjuvant chemotherapy and discharged and discontinued follow-up. It was a prospective study. A proforma was designed for each patient which included, name, age, complaints, parity, menopausal status, past and family history and associated medical condition were asked.

Examination included, general physical examination, systemic examination which included, cardiac system, respiratory system, per abdominal, per speculum, per vaginal and per rectal examination. These patients with pelvic masses were subjected to further investigation. Routine investigations, ultrasonography and serum CA125 levels were done in all patients. CT scan in patients who were affordable. Investigations like LDH, beta HCG, AFP done if necessary. Ultrasonographic score was calculated as shown in Table 1.

Inclusion criteria

Postmenopausal women presenting as ovarian masses and admitted for evaluation and management.

Exclusion criteria

Women already diagnosed as ovarian cancer by histopathology and have received chemotherapy.

Table 1: Ultrasonographic scoring.

Findings	Score
Unilocular simple cyst with regular fine wall or lesion suggestive of dermoid	0
Multilocular cyst with regular and smooth wall (<3mm) or thick (>3mm) or solid homogenous tumor with hyperechogenic well defined wall	1
Unilocular or multilocular cyst with fine wall or irregularity in septa (thickness > 3mm)	2
Multilocular cyst with thick and irregular wall (irregularity <3mm) and or irregular septa or cyst or papillary irregularity > 3mm	4
Complex lesion with predominance of cystic or solid area without irregularity in surface	5
Multiplicity: unilateral or bilateral lesion	10
Associated lesion	1
Wall expansive invasion > 3mm	2

All patients were subjected to laprotomy/laprosopy. Total abdominal hysterectomy with bilateral salpingo-oophorectomy, cystectomy, unilateral or bilateral salpingo-oophorectomy were done in intra operatively benign appearing lesions and a surgical staging done for those with malignant masses with optimal debulking including total abdominal hysterectomy with bilateral salpingo-oophorectomy was done. Specimen subjected for histopathological analysis. Patients whose mass was malignant were given further treatment with chemotherapy.

The trial was begun to compare RMI1 and RMI 2 with each other. Preoperative serum CA 125 levels, ultrasound findings, and menopausal status were noted. The ultrasound was performed transabdominally by 5-2 MHz transducer of IU 22 Philips. A score was assigned for the ultrasound features namely presence of multilocular cystic lesion, solid areas, bilateral lesion, ascites, and intraabdominal metastasis.

A total ultrasound score was thus calculated for each patient as shown in Table 1. Tumor size (s) was measured by ultrasound for each patient. Postmenopausal status was defined as more than one year of amenorrhea or age older than 50 years in woman who had undergone hysterectomy.

Serum samples were collected preoperatively and serum CA 125 levels were measured using Electrochemiluminescence immunoassay (ECLIA). Based on the data obtained RMI1 and RMI2 were calculated as follows:

- $RMI\ 1 = U \times M \times CA\ 125$, where a total ultrasound score of 0 made $U = 0$, a score of 1 made $U = 1$, and a score of > 2 made $U = 3$: premenopausal status made $M=1$ and postmenopausal $M = 3$. The serum level of CA 125 in U/ml was applied directly to the calculation.⁶

- RMI 2 = U x M x CA 125, where a total ultrasound score of 0 or 1 made U = 1 and a score of >2 made U = 4; premenopausal status made M = 1 and postmenopausal M = 4. Serum levels of CA 125 was applied directly to the calculation.^{7,8}

The histopathological diagnosis was considered the gold standard for definite outcome. All statistical analysis was performed using the SPSS version 17 (trial version). The chi-square test was used to test differences in distribution of age, menopausal status, CA125 and ultrasound score and for RMI1 and RMI2. Pearson chi-square test was used. The sensitivity was defined as the percentage of patients with malignant disease having a positive test result. The specificity was defined as percentage of benign disease having a negative test result. The positive predictive value was defined as the percentage of patients with positive test result having malignant disease and the negative predictive value was defined as the percentage of patients with a negative test result having benign disease. It was calculated for all the individual parameters and for RMI1 and RMI2.

RESULTS

Adnexal masses can be non invasive (benign neoplastic, non neoplastic or functional) or invasive (malignant). Non invasive lesions include benign lesions namely serous and mucinous cystadenoma, mature teratoma, spindle cell tumor, ovarian fibroma and non neoplastic lesions like ovarian endometriosis, cystadenofibroma, fibrocollagenous tumor, simple ovarian cyst, fimbrial cyst, corpus luteal cyst, salpingo-ophoritis, ectopic pregnancy, sclerosing ovarian tumor, necrotic tissue due to torsion. Invasive lesions are serous and mucinous cystadenocarcinoma, Brenner tumor, yolk sac tumor, granulose cell tumor, adenocarcinoma of fallopian tube, krukensberg tumor. In the following tables the distribution of adnexal masses has been done according to final HPR diagnosis. Out of 99 patients 83 (83.8%) had benign lesions and 16 (16.16%) had malignant lesion. Most of the tumors were found to be between 30-50 years as seen in Table 2.

Table 2: Age wise distribution of adnexal masses.

Age	HPR		Total
	Non-invasive	Invasive	
<30	16	1	17
30-50	47	9	56
>50	20	6	26
Total	83	16	99

Chi-square test Value: 2.244, P Value: 0.326 (non significant).

Out of 99 patients 17 were less than 30 years of age and only one had malignant lesion among them. Between 30 to 60 years 9 had invasive lesion and 47 had non invasive lesion. In age group more than 50 years 6 had invasive lesion and 20 had non invasive lesion. Age as individual

factor is not significant in predicting type of adnexal mass.

Table 3: Menopausal status in relation to adnexal masses.

Menopausal status	HPR		Total
	Non-invasive	Invasive	
Post menopausal	26	7	33
Pre menopausal	57	9	66
Total	83	16	99

Chi-square test value: .932 P value: .334 (non significant).

Out of 33 women who were postmenopausal, 26 (78.78%) had non invasive and 7 (21.21%) had invasive lesion. Among 66 pre menopausal women 57 (86.36%) had non invasive and 9 (13.63%) had invasive lesion which is non significant (P value: 0.334) as seen in Table 3. The sensitivity, specificity, positive and negative predictive are 31.32%, 56.25%, 78.78% and 13.63% respectively. Percent of false negative is 68.67% and percent of false positive is 43.75%. This suggests that menopausal status when taken as a single criteria is non significant in differentiating type of adnexal mass.

Table 4: Frequency of symptoms.

Symptoms	Frequency in percent
Pain abdomen	82
Mass abdomen	31
pv bleeding	19
Urinary symptoms	10
White discharge p v	4
Decreased appetite	2
Weight loss	4

pv- per vaginal.

Most of the patients presented with pain abdomen (82%) and mass abdomen (31%).

Patients less frequently presented with per vaginal bleeding (19%), urinary symptoms (10%), white discharge per vaginum (4%), decreased appetite (2%) and weight loss (4%) as cited in Table 4.

Ultrasonography is an important tool in diagnosis of adnexal masses. Various characteristics of the tumor was given different score as depicted in Table 1 and USG score (U) was calculated for each tumor. A score of 0-1 suggested a benign tumor whereas score of 2 or more suggested a malignant tumor. This score as individual criteria was compared with the final histopathological diagnosis of the adnexal mass and its sensitivity and specificity and positive predictive value calculated. It is seen in the Table 5 that out of 40 who had a score of 0 or 1 all had non invasive lesion and out of 59 who had USG score of 2, 43 were non invasive and 16 were invasive and was significant (p value 0.000). Sensitivity of single

criteria USG by score U value has a sensitivity of 48.1%, specificity of 100%, positive predictive value of 100% and negative predictive value of 27%. Percent of false negative is 51.8% and percent of false positive is 0%.

Table 5: Relation of USG score with adnexal mass.

USG score	HPR		Total
	Non-invasive	Invasive	
0-1	40	0	40
2 or more	43	16	59
Total	83	16	99

Chi-square value: 12.93 P value: 0.000(significant).

When a cut of level of 35 U/ml was considered and any value less than 35U/ml suggested a benign or non invasive lesion and value of equal to or above 35 U/ml suggested an invasive or malignant tumor, out of 76 patients whose CA125 levels were less than 35U/ml, 72 had non invasive lesion and 4 were invasive. 23 patients who had value of CA125 >35U/ml, 11 were non invasive and 12 were invasive. P value was significant (.000) as seen in Table 6. Sensitivity of single criteria CA125 in U/ml value has a sensitivity of 86.74%, specificity of 75% and positive predictive value of 94.73% and negative predictive value of 75%. Percent of false negative is 13.25% and percent of false positive is 25%. CA125 is a marker specific to epithelial tumors. When only epithelial tumors were taken into consideration to know predictability of CA125 out of 27 cases of serous cystadenoma 21 had CA125 U/ml value of less than 35U/ml and 6 had a value of more than or equal to 35. Most of the values were marginally raised and none were as high as 600. The highest value was 185 U/ml. Among 19 cases of mucinous cystadenoma 18 had CA125 level less than 35 U/ml and only one case had level more than 35 and which was 38.5 U/ml.

Sensitivity of single criteria CA125 in U/ml value in predicting type of adnexal mass in epithelial ovarian tumors it has a sensitivity of 84.75%, specificity of 88.88% and positive predictive value of 97.5% and negative predictive value of 53.33%.

Table 6: Relation of CA125 with adnexal mass.

CA125	HPR		Total
	Non-invasive	Invasive	
<35	72	4	76
>35	11	12	23
Total	83	16	99

Chi-square value: 28.676 p value: 0.000 (significant).

When tumor size of less than 7 taken as cut off, out of 23 patients, 22 had non-invasive and 1 had invasive lesion. 76 of them had tumor size of 7 or more and among them 61 had non invasive and 15 had invasive lesion as seen in Table 7. Sensitivity, specificity, positive and negative predictive of tumor size was 26.5%, 93.75%, 95.65% and

19.73% respectively. Percent of false negative is 73.49% and percent of false positive is 6.25%.

Table 7: Relation of tumor size with adnexal mass.

Tumor size	HPR		Total
	Non-invasive	Invasive	
6.99	22	1	23
7.00	61	15	76
Total	83	16	99

Chi-square value: 3.086 P value: .079(non significant).

Table 8: Comparison of individual parameters.

Individual parameters	Menopausal status	Ultra-sound score	CA125	Size
Sensitivity	31.32	48.1	86.74	26.5
Specificity	56.25	100	75	93.75
PPV	78.78	100	94.73	95.65
NPV	13.63	27	75	19.73
% of FN	68.67	51.8	13.25	73.49
% of FP	43.75	0	25	6.25

Table 9: Distribution of ovarian lesions by histopathological diagnosis.

	Frequency	Percent
Invasive lesions		
Serous cystadenocarcinoma	7	7.1
Mucinous cystadenocarcinoma	2	2.0
Papillary adenocarcinoma of fallopian tube	1	1.0
Brenner tumour	2	2.0
Granulosa cell tumor	2	2.0
Krukenberg tumour	1	1.0
YOLK sac tumor	1	1.0
Non invasive lesions		
Serous cystadenoma	27	27.3
Mucinous cystadenoma	19	19.2
Teratoma	5	5.0
Salpingo-oophoritis	4	4.0
Ectopic pregnancy	1	1.1
Ovarian endometriosis	1	1.1
Others	26	19.2
Total	99	100.0

Others include corpus luteal cyst, follicular cyst, sclerosing tumor of ovary, ovarian fibroma, twisted ovarian cyst with necrosis, simple serous cyst, fimbrial cyst, spindle cell tumor.

Among all patients who were evaluated for RMI1, 77 were benign and out of these 73 had non invasive lesion and 4 had invasive lesion in histopathology. 22 were malignant as assessed by RMI1 and 10 of them had non invasive lesion and 12 had invasive lesion in histopathology. The sensitivity of RMI1 is 87.95%, specificity is 75%, positive predictive value is 94.8%, negative predictive value is 54.54%, percentage of false

negative is 12.04% and percentage of false positive is 25% as seen in Table 9.

Among all patients who were evaluated for RMI2, 75 were benign and out of these 72 had non invasive lesion and 3 had invasive lesion in histopathology. 24 were malignant as assessed by RMI2 and 11 of them had non invasive lesion and 13 had invasive lesion in histopathology. The sensitivity of RMI2 is 86.74%, specificity is 81.25%, positive predictive value is 96%, negative predictive value is 54.16%, percentage of false negative is 13.25% and percentage of false positive is 18.75% as seen in Table 10.

Table 10: Correlation of RMI1 with histopathological report.

RMI1	HPR		Total
	Non-invasive	Invasive	
Benign	199	73	77
Malignant	200	10	22
Total	83	16	99

Chi-square value 30.75 and p value 0.000.

Various types of invasive lesions were detected in histopathology. Out of 16 invasive tumors serous cystadenocarcinoma found in 7, mucinous cystadenocarcinoma in 2, papillary adenocarcinoma of fallopian tube in 1 patient, brenner tumour in 2, granulosa cell tumor in 2, krukenberg tumor in 1, yolk sac tumor in 1 patient. Among benign tumors most commonly diagnosed was serous cystadenoma in 27 patients, mucinous cystadenoma in 19, teratoma in 5, salpingo-oophoritis in 4, ectopic pregnancy 1 patient, and ovarian endometriosis in 1. 26 had lesions in others category as depicted in Table 12

Table 11: Correlation of RMI2 with histopathological report.

RMI2	HPR		Total
	Non-invasive	Invasive	
Benign	199	72	75
malignant	200	11	24
Total	83	16	99

Chi-square test value: 33.77 P value: .000 (very significant).

Table 12: Correlation of RMI1 and RMI2 with respect to sensitivity, specificity, positive predictive value, negative predictive value and percentage of false negative and false positive value.

	RMI1	RMI2
Sensitivity	87.95	86.74
Specificity	75	81.25
PPV	94.8	96
NPV	54.54	54.16

PPV: positive predictive value, NPV: negative predictive value. Cut off 200 for RMI1, RMI2.

DISCUSSION

The study conducted in KIMS Hubli, has been compared with the study in Department of Obstetrics and Gynecology of Gulhane Military Medicine Academy, Etlik 06010 Kecioren, Ankara, Turkey for surgical exploration of surgical masses conducted between October 1, 2008, and February 3, 2010. 100 women with pelvic masses admitted and evaluated for CA125.⁹ Ultrasound score and menopausal status and pre operative RMI1 and RMI2 calculated and then compared with histopathological diagnosis. According to this study, 80% had benign and 20% had malignant lesion which was similar to present study (83.83% and 16.16% respectively). The mean CA125 was significantly higher among women with malignancy when compared with women with benign lesion (329.23 U/ml versus 28.03 U/ml). When individual parameters were compared CA125 had better sensitivity than ultrasound, size and menopausal status. Even though others had higher specificity than CA125, there was considerable loss of sensitivity which is important in suspecting malignancy. In the study the Sensitivity, specificity, positive predictive value and negative predictive values of individual parameters were calculated and compared with the study. In the study both CA125 and ultrasound were efficient in differentiating an adnexal mass and p value was significant (p value .000 and .000 respectively). Menopausal status and size were insignificant (0.334 and 0.075 respectively). When cut off value of 200 for RMI1 and RMI2, the results are as in Table 9.⁹ The study revealed that the usefulness of RMI to correctly distinguish benign from malignant pelvic masses. In the study it was found that efficiency of RMI1 and RMI2 were similar to the Gulhane Military Medicine Academy. The study had higher sensitivity when compared to Gulhane military Academy.¹⁰

The sensitivity of RMI in Singapore study was very less due to high incidence of endometriosis in their study Also the present study was compared with study conducted in National University Hospital and Yong Loo Lin School of Medicine, Singapore.³ Total of 228 patients were studied in between November 2004 to October 2009. 7.5% (17) had malignant lesion and 92.5% (211) had benign pathology. Individual variables analyzed showed significant differences in median CA125 and tumor size (p = .044 and p<0.0005, respectively) where as in the study CA125 and ultrasound were significant (p value .000 and .000 respectively), the menopausal status and size of tumor were not significant (.334 and .075 respectively). Also in this study the efficiency of RMI at various cut off values was also studied and concluded that 200 is the best cut off and had highest sensitivity and predictive value. The study was confounded by large cases of ovarian endometriotic cysts that presented as complex ovarian cysts with both high CA125 levels and ultrasonographic scores. Such a confounding factor was not found in the study as only one case of ovarian endometriosis was detected. Other limiting factors in that

study were a retrospective nature, small sample size and possible interobserver variability. The study is a prospective one but latter limiting factors also existed in the study too.

CONCLUSION

The conclusions of the study are thus, there is no definitive screening method in diagnosing ovarian tumor. Surgery is the prime modality of treatment in ovarian malignancy. It is of great importance to diagnose ovarian malignancy preoperatively so that an optimal surgery at a tertiary centre is planned. Optimal surgery is the most important predictor of survival of the patient and minimal residual tumor mass (<.5 cm) is aimed to improve survival and also to increase efficiency of post operative chemotherapy which can be no doubt done only in a tertiary care centre in the hands of an expertise surgeon. The study aims to find the efficiency of individual parameters namely menopausal status, ultrasound, CA125 and tumor size in pre operative evaluation of adnexal masses. The study also aims to find efficiency of RMI1 and RMI2 and to compare between them. The study conducted by us showed that individual parameters like CA125 and ultrasound were statistically significant in differentiating an adnexal mass as non invasive (benign) or invasive (malignant). (p value 0.000 and 0.000 respectively), but menopausal status and size of tumor were not significant hence non efficient in pre operative evaluation (p value 0.334 and 0.079 respectively). RMI1 and RMI2 were statistically significant in differentiating invasive from a non invasive lesion. The RMI1 is more efficient (sensitivity 87.95%) compared to RMI2 (sensitivity 86.74%). There was no statistically significant difference in performance of RMI1 and RMI2 at a cut off of 200. Compared to individual parameters RMI1 and RMI2 are definitely more efficacious in pre operative diagnosis of adnexal masses. The study had a small sample size of 100. The study also had the possibility of interobserver variability in ultrasound score. Thus small sample size and interobserver variability were the confounding factors of the study.

Thus RMI is a simple, easily applicable tool in a general gynaecological setting and primary health care setting so that patient can be referred to tertiary centre for an optimal therapy.

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