

DOI: <http://dx.doi.org/10.18203/2320-1770.ijrcog20171385>

## Original Research Article

# Risk of malignancy index in ovarian tumour for predicting ovarian malignancy by using Jacob's score

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**Received:** 06 March 2017

**Revised:** 13 March 2017

**Accepted:** 19 March 2017

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### ABSTRACT

**Background:** Ovarian malignancy is the most common gynecological malignancy after the cancer of the cervix. A woman's risk at birth of ovarian cancer at some time in her life is 1 % to 1.5% and that of dying from cancer is almost 0.5 %. The most commonly occurring ovarian tumors are of epithelial in origin. It has the highest case-fatality ratio of all gynecological malignancies. Hence the early diagnosis is the most important factor for better prognosis. A clinical evaluation of the patient, followed by ultrasonography and CA-125 is helpful. This study aims to determine the role of Risk of Malignancy Index (Jacob's RMI) in ovarian tumors for prediction of ovarian malignancy.

**Methods:** This is a prospective cohort study. The present study was carried out at department of OBG, in collaboration with the Departments of Radio diagnosis and Pathology, AHRR, New Delhi. 100 patients meeting the inclusion and exclusion criteria were considered. Detailed clinical history, examination and ultrasonography (Abdomen and pelvis) were done. Estimation of CA125 was done thereafter. Calculated JACOBS RMI score was compared with operative surgical staging and histopathological-cytological examination of the specimen. Data obtained thereafter was analysed using appropriate and relevant statistical software.

**Results:** In present study sensitivity of RMI Score in the pre-menopausal women was 66.7% and in post-menopausal women was 83.3%. Specificity of RMI Score in the pre-menopausal women was 96.3% and in post-menopausal women was 81.8%. The positive predictive value in the pre-menopausal women was 40% and in post-menopausal women was 71.4%. The negative predictive value in the pre-menopausal women was 98.7% and in post-menopausal women was 90%. Diagnostic accuracy in a case of premenopausal women was 95.2% and 82.4% for postmenopausal women.

**Conclusions:** The present study shows that RMI Score helps in identifying effectively those patients who require Staging Laparotomy and hence referral to Gynecologist Oncologist. Patients with ovarian masses with low risk of malignancy index can be treated by minimal access procedures.

**Keywords:** CA125, Ovarian tumors, Risk of Malignancy Index score

### INTRODUCTION

Ovarian cancer is the fifth most common cause of cancer deaths in females and is mostly detected very late in course of disease. Ovarian cancer has been defined as an occult disease of insidious onset with non-specific clinical symptomatology-hence possesses the greatest

clinical challenge of all the gynaecological malignancies. The site of lesion renders it inaccessible to simple methods of anatomical diagnosis such as smears, biopsy and curettage as in case of cervix and corpus uteri tumours. Thus, when faced with a patient with ovarian mass, a thorough assessment of the likelihood of malignancy is extremely essential. A clinical evaluation

of the patient, followed by ultrasonography and CA-125 is helpful. On this basis, the patient may be further grouped as per the presence or absence of peritoneal spread, as indicated by ascites, associated with the ovarian mass.<sup>1,2</sup>

The high mortality rate in ovarian malignancy is mainly due to late detection of disease. If it can be detected at an early stage then disease can be treated with optimal primary cytoreduction and achievement of optimal cytoreduction (single most important prognostic criteria) becomes possible. Currently available screening test for ovarian cancer include- Pelvic examination, Tumor markers (CA-125), TAS, TVS with Color Doppler, CT-Scan, MRI. Use of multimodality screening (CA-125 followed by TVS) can increase sensitivity to 99.9%, a specificity of 78.9% and a positive predictive value of 26.8% at one year follow up. It is clear that the multimodality screening using sequential CA-125 measurement and ultrasound achieve a high specificity and encouraging sensitivity in screening ovarian cancer.<sup>3</sup>

Pelvic examination is not specific and sensitive in detecting ovarian malignancy. Cancers detected by pelvic examination are often far advanced, so pelvic examination for screening is not recommended.<sup>4</sup> Tumour markers when used alone are not specific to be used as screening test. They are raised in a number of benign conditions and are not raised in poorly differentiated cancer, borderline tumours and mucinous tumours. In a prospective study conducted to evaluate sensitivity and specificity of CA-125 as a marker for ovarian malignancy and concluded that measurement of serum CA-125 levels, particularly at a reference value of 35 IU/mL, is not sufficiently sensitive to be used alone as a screening test for the detection of ovarian cancer. Lower CA-125 reference values could identify women at higher risk of developing ovarian cancer, but CA-125 measurement cannot be recommended for this purpose because of the high proportion of women who would be falsely classified as being at high risk for developing ovarian cancer.<sup>5</sup> TAS and TVS have better accuracy in detecting ovarian cancer. TVS has a better resolution as compared to TAS. Ultrasonography can differentiate between solid, cystic and multilocular masses. Although malignancy cannot be diagnosed; unequivocally the complexity of the masses was suspicious of malignancy.<sup>6</sup> Complex lesions with solid areas and thick setae were indicative of malignancy.<sup>7</sup> Criterion to differentiate benign from malignant ovarian tumours with 91% success rate includes: size of the lesion, unilocular or multilocular, presence of thick (>3mm) or thin septa, presence of solid nodules and evidence of invasion of capsule or fixation of masses.<sup>8</sup>

### **Role of risk of malignancy index (RMI)**

Risk of malignancy index is able to correctly discriminate between malignant and benign neoplasm of ovary. It is a scoring system which can be introduced

easily into clinical practice to facilitate the selection of the patient for primary surgery at an oncological unit. RMI in ovarian malignancy incorporates CA-125, USG and Menopausal status for the accurate prediction of likely ovarian cancer in preoperative period. RMI is useful in the following-Predicting if an ovarian mass is malignant or benign, screening for suspected pelvic mass, deciding appropriate management protocol and triage management.

Jacobs RMI Score (RMI I) -Total Score = USG Score X Menopausal Score X CA -125(U/ml)

USG score: 0 - No risk factor, 1 - One risk factor, 3 - Two - Five risk factors. High risk factors in USG: Multiloculated cysts, solid areas, bilateral lesions, ascites and evidence of metastasis. Menopausal status: 1- Pre-menopausal, 3 - Post-menopausal CA125- Absolute value (IU/ml).

Score <200 - Low risk (risk of ovarian malignancy is 0.15 times)

Score >200 - High risk (risk of ovarian malignancy is 42 times)

(When 200 is taken as cut -off for RMI, Sensitivity is 85%, Specificity is 97%).<sup>9</sup>

### **Tingulstad RMI Score (RMI II)**

USG Score-0-0-1-No risk factor, 4-≥2 risk factor. High risk factors in USG- Multi lobulated cysts, solid areas, bilateral lesions, ascites and evidence of metastasis. Menopausal status: 1-Pre-menopausal, 4-Post-menopausal. CA125- Absolute value (IV/ml).

Score <125 - Low risk of malignancy

Score >125 - High risk of ovarian malignancy

It was found that RMI II performed better than RMI I, this was confirmed by some studies but some did not find any differences in performance of the three RMI scoring systems. RMI II has limitations in borderline and stage I invasive tumour. 83% of borderline and 44% of stage I invasive tumour have RMI <200, although clinical relevance of these findings seems limited.<sup>10</sup>

## **METHODS**

This prospective cohort study was conducted at AHRR Delhi. All patients with suspected ovarian malignancy visiting the OPD who gave consent were included in the study. Patients with history of bilateral oophorectomy, active malignancy (women with previous history of malignancy with no documented persistent or recurrent disease were eligible) and previous history of ovarian cancer were excluded from the study.

Post-menopausal women were defined as those with more than one year of amenorrhea or age more than 50

years for women who had their hysterectomy done. All other women who did not meet the above criteria were considered pre-menopausal. Ultrasonography of abdomen and pelvis was done. CA-125 (IU/ml) estimation using fully Automated Bidirectional Interphase Chemiluminescent Immunoassay was done. 100 patients meeting the inclusion and exclusion criteria who consented to take part in the study were considered. Detailed Clinical history of the patient was taken and thorough clinical examination was done. Ultrasonography (Abdomen and pelvis) was done to ascertain the High-risk status-multiloculated cysts, solid lesions, ascites, bilateral lesions, and evidence of metastasis. Estimation of CA125 was done thereafter. Calculated JACOBS RMI score was compared with operative surgical staging and histopathological-cytological examination of the specimen. Data so obtained thereafter was analyzed using appropriate and relevant statistical software. The statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 15.0 statistical Analysis Software. All the information regarding patients was not disclosed in any circumstance. At any time of the study the patient had a right to ask any questions with regards to any aspect of the study.

## RESULTS

A total of 100 women with suspected ovarian malignancy were enrolled in the study. Details related to age, obstetric and personal history, signs and symptoms were noted and they were subjected to USG, CA125 assessment and histopathology. Final diagnosis was made on the basis of the findings of histopathological examination. On the basis of results of histopathology, the patients were dividing into two groups.

**Table 1: Age-wise Distribution of cases.**

Age ( yrs )	Benign	Malignant
<10	0	0
11--20	3(4.68%)	0
21-30	13(20.31)	5(13.8)
31-40	17(6.5)	7(19.44)
41-50	10(15.6)	6(16.66)
51-60	6(9.3)	11(30.55)
61-70	8(12.5)	4(11.11)
71-80	5(7.81)	3(8.33)
81-90	1(1.56)	0
91-100	1(1.56)	0
<b>Total</b>	<b>64</b>	<b>36</b>

Table 1 shows that in the present study, the incidence of Benign ovarian tumor is 64 % and that of malignant ovarian tumor is 36 % in all the patients presenting with adnexal mass and clinically suspected of ovarian malignancy. The incidence of ovarian tumor was found in all age groups. In the present study the age of the youngest patient was 17 years and that of the oldest

patient was 92 years. Total 55 patients were premenopausal and 45 were postmenopausal. 24 cases were between the age group of 31 to 40, 16 cases between 41 to 50 years and 17 cases between 51 to 60 years. Most of the benign tumors were seen in 3<sup>rd</sup>, 4<sup>th</sup> and 5<sup>th</sup> decade of life; while the malignant tumors had an age distribution mostly in 4<sup>th</sup>, 5<sup>th</sup> and 6<sup>th</sup> decade of life. The overall mean age of patients was 45.5±8.50 years.

**Table 2: Distribution of patients in two groups according to symptoms.**

Symptoms and signs	Benign (n=64)	Malignant (n=36)
Dyspepsia	22(34%)	13(36%)
Pain lower abdomen	56(88%)	35(95%)
Distension	18(28%)	18(50%)
Bowel and bladder symptoms	6(9.3%)	7(19.4%)
Menstrual abnormality	20(31%)	7(19.4%)
Loss of appetite	10(15.6%)	13(36%)
<b>Signs</b>		
Abdominopelvic mass	24(37.5%)	30(83%)
Ascites	4(6.2%)	19(52%)

According to Table 2, Dyspepsia was present in 34 % benign cases and 36% malignant cases. Pain abdomen was associated in 88% benign cases and 97% malignant cases. Distension of abdomen was found in 28% benign and 50% malignant cases. 37.5% benign cases and 83% malignant cases had lump abdomen. Bowel and bladder irregularities were found in 19.4% malignant and 9.3% benign cases. Menstrual irregularities were present in 31% benign and 19.4% malignant cases. Loss of appetite was found in 15.6% of the malignant cases and 36 % malignant cases. The proportion of patients in malignant group as compared to benign group was higher for symptoms of pain lower abdomen, dyspepsia, distention, lump abdomen, bowel and bladder symptoms and loss of appetite. Whereas it was higher in benign group in case of menstrual abnormality. Compared to benign group, the proportion of subjects with clinical sign such as ascites and abdominopelvic mass was higher in the malignant group. The difference was also found to be significant statistically for the clinical sign of ascites and abdominopelvic mass ( $p < 0.010$ ). According to table 03, Menopausal status was observed to increase all the parameters; the sensitivity of the marker increased from 41.60% to 94.70 %, PPV increased from 46.80 % to 69.20%. Substantial increase in specificity (10.50% to 69.20%) and NPV (8.60% to 94.70 %) was observed, thus indicating that incidence of malignancy increased rapidly in post-menopausal women as compared to pre-menopausal. Overall diagnostic accuracy showed an increase from 30% to 80%.

**Table 3: Comparison of diagnostic efficacy of CA-125 level in premenopausal and post-menopausal patients to detect malignancy.**

Premenopausal					
SN	Ca125	Benign		Malignant	
01	≥35	No	%	No	%
		17	89.5	15	42
02	≤35	02	10.5	21	58
Sensitivity	Specificity	PPV	NPV	Diagnostic accuracy	
41.60	10.5	46.8	8.6	80%	
Post-menopausal					
SN	Ca 125	Benign		Malignant	
	>35	No	%	No	%
01		08	31	18	95
02	<35	18	69	01	05
Sensitivity	Specificity	PPV	NPV	Diagnostic accuracy	
94.7%	69.20%	69.20%	94.7%	80%	

**Table 4: Diagnostic agreement between CA 125 levels and USG scores.**

CA- 125 and USG			
	Ca-125score		Total
	≥35	<35	
USG			
>3	37	15	52
<3	20	28	48
<b>Total</b>	<b>57</b>	<b>43</b>	<b>100</b>

$\kappa = 0.296$ ;  $p = < 0.05$

Table 4 shows that on evaluation of agreement between CA 125 and USG, a fair agreement was observed between the two. Out of 57 subjects with CA 125 ≥35 IU/ml, USG score >3 was observed in only 37(64.9%) while out of 43 subjects with CA 125 score < 35 IU/ml, only 28 (65.1%) had USG score <3.

**Table 5: Diagnostic agreement between CA125 levels and RMI score.**

RMI score and CA-125			
CA-125	RMI score		Total
	>200	<200	
≥35	38	19	57
≤35	0	43	43
<b>Total</b>	<b>38</b>	<b>62</b>	<b>100</b>

$\kappa = 0.632$ ;  $p = < 0.001$

According to table no 05, total of 38 cases had RMI score >200 had CA 125 score >35 IU/ml (100%). For 62 subjects having RMI score <200, 43 (69.35%) had CA 125score <35IU/ml. On evaluating the data statistically, the extent of agreement between two groups was found to be substantial ( $\kappa = 0.632$ ) with a very high significant level ( $p < 0.001$ ).

**Table 6: Menopausal status and USG as a marker of malignancy.**

Pre-menopausal (n=55)					
SN	USG score	Benign		Malignant	
		No.	%	No.	%
1	≥3	16	41	10	62.5
2	<3	23	59	6	37.5
Sensitivity	Specificity	PPV	NPV	Diagnostic Accuracy	
62	58	38	79	60	
Post- menopausal (n=45)					
SN	USG score	Benign		Malignant	
		No	%	No	%
1	≥3	9	36	17	85
2	<3	16	44	3	15
Sensitivity	Specificity	PPV	NPV	Diagnostic Accuracy	
85	64	65.3	84.2	73.3	

According to Table 6, in pre-menopausal group, the specificity was 58%, the positive predictive value was only 38%. All the five parameters found to be increased in post-menopausal group as compared to premenopausal group, increasing the change in overall diagnostic accuracy from 60 to 73%. For USG, the positive predictive value was only 38% for pre-menopausal and 65.3% for post-menopausal subjects, thereby showing the test to be 27% more positive predictive value among post- menopausal subjects as compared to premenopausal subjects. For patients with USG score <3, negative predictive value for pre-menopausal group was 79% as compared to 84.2% in post-menopausal group showing not a much difference in both groups.

According to Table 7, there was a fair agreement between RMI score and USG score. 30 out of 38(80%) cases

having RMI score > 200 had USG score 3; however, same extent of agreement was not observed for RMI score <200 where only 40 out of 62 (45%) cases had USG score <3. Overall an agreement of 62% was observed between the two techniques. On evaluating the data statistically, the extend of agreement between two groups was found to be very fair ( $\kappa=0.406$ ) with a very high significance level ( $p<0.001$ ), thus implying that the variability agreement between two techniques is not merely by chance, rather it is significant statically too ( $p=0.001$ ).

**Table 7: Diagnostic agreement between RMI score and USG scores.**

RMI score and USG score			
USG score	RMI score		Total
	>200	<200	
3	30	22	52
<3	8	40	48
<b>Total</b>	<b>38</b>	<b>62</b>	<b>100</b>

$\kappa=0.406$ ;  $X^2=17.83$ ;  $p<0.05$

**Table 8: Diagnostic efficacy of RMI score as a market of malignancy.**

RMI score	Outcome			Total
	Malignant	Benign		
>200	29	9		38
<200	7	55		62
Total	36	64		100
Sensitivity	specificity	PPV	NPV	Diagnostic Accuracy
80.5%	85.9%	76.3%	88.7%	84%

According to table 08, RMI score >200 was a good predictor having both adequate sensitivity (80.5%) and specificity (85.9%), an average positive predictive value (76.3%) and very good negative predictive value (88.7%). Overall the diagnostic accuracy was very good (84%). According to table 09, as compared to pre-menopausal age group, in the post-menopausal age group

the sensitivity and positive predictive value increase, however, the specificity decreased, thus showing a relatively higher incidence of false positivity in post-menopausal age group. Overall diagnostic accuracy was found higher in post-menopausal (86.6%) as compared of pre- menopausal age group (81.8%). However, for RMI, the positive predictive value for malignancy was higher in post-menopausal group (80%) as compared to pre-menopausal group (70%), the negative predictive value too was higher in post-menopausal group (91%) as compared to pre-menopausal group (86%).

**Table 9: Menopausal status and RMI as a marker of malignancy.**

Pre-menopausal (n=55)					
SN	RMI score	Benign		Malignant	
		No.	%	No.	%
1	≥ 200	5	9.1	12	22
2	< 200	33	60	5	9.1
Sensitivity	Specificity	PPV	NPV	Diagnostic Accuracy	
70.5	86.8	70.5	86.8	81.8	
Post –menopausal (n=45)					
SN	RMI score	Benign		Malignant	
		No.	%	No.	%
1	≥ 200	4	8.8	17	13.7
2	< 200	22	48.8	2	4.4
Sensitivity	Specificity	PPV	NPV	Diagnostic Accuracy	
89.4	84.6	80.9	91.6	86.6	

According to Table 10, all the cases predicted to be malignant by any of the method and those who were detected to be likely malignant on laparoscopy were subjected to laparotomy. Laparoscopy was reserved for the patients who had a likely likelihood of being pathology on the basis of RMI score. 18.4 % women with RMI score >200, who otherwise had benign pathology underwent laparotomy.

**Table 10: Association of different diagnostic techniques with operative procedure and malignancy status.**

	CA 125 $\geq$ 35 IU/ML		CA 125 <35IU/ML	
	Malignant (n=33)	Benign (n=25)	Malignant (n=3)	Benign (n=39)
Laparoscopy	0	14	2	22
Laparotomy	33	11	1	15
	USG Score 3		USG <3	
	Malignant (n=28)	Benign(n=24)	Malignant (n=8)	Benign(n=40)
Laparoscopy	1	11	2	25
Laparotomy	27	13	6	15
RMI	RMI score >200		RMI score <200	
	Malignant (n=29)	Benign (n=9)	Malignant (n=7)	Benign (n=55)
Laparoscopy	1	2	3	33
Laparotomy	28	7	4	22



All of the 33 patients who were thought to be malignant by CA-125 and also confirmed to be having malignant pathology underwent laparotomy.

There were 22 patients who were predicted were to be having benign pathology by CA-125 level  $>35$  IU/ml but confirmed to be malignant subjected to laparoscopy. One patient was subjected to Laparotomy despite being predicted to be having benign pathology by CA-125 level found to be having malignant pathology. Three cases detected to be negative for malignancy by RMI score but confirmed to be malignant on HPE examination underwent Laparotomy. Out of 28 cases predicted to be malignant on USG score of 3, only one case was subjected to laparoscopy and confirmed to be malignant rest all subjected to Laparotomy.

**Table 11: Histopathological findings.**

Type of tumor		No. of cases (%)
Benign tumors Total: 64%	Serous cyst adenoma	11 (17.18%)
	Mucinous cyst adenoma	10 (16.6%)
	Dermoid cyst	7 (10.9%)
	Corpus luteal cyst	4 (6.25%)
	Endometrioma	17 (26.56%)
	Follicular cyst	8 (12.5%)
	Para-ovarian cyst	2 (3.1%)
	Fibroma ovary	3 (4.6%)
	Struma ovarii	1 (1.5%)
	xanthogranulomatous inflammation	1 (1.5%)
Type		No. of cases (%)
Malignant tumors Total: 36%	Serous cyst adenocarcinoma	21 (58.3%)
	Mucinous cyst adenocarcinoma	6 (16.6%)
	Clear cell carcinoma	2 (5.5%)
	Adult granulosa cell tumor	2 (5.5%)
	Malignant Brenner tumor	2 (5.5%)
	Yolk sac tumor	1 (2.7%)
	Sertoli cell tumor	1 (2.7%)
	Endometrial stromal sarcoma	1 (2.7%)

According to Table 11, amongst benign ovarian tumors, endometrioma was the most common ( $n=17$ ; 26.56%), followed by serous cyst adenoma ( $n=11$ ; 17.18%) while Struma ovarii ( $n=1$ ; 1.5%) was least common diagnosis. Serous cyst adenocarcinoma was the most common ( $n=21$ ; 58.3%) was the most common malignant from followed by mucinous cyst adenocarcinoma ( $n=6$ ; 16.6%).

## DISCUSSION

In our study, the incidence of the Benign Ovarian Tumor in all the patients presenting with adnexal mass and clinically suspected of ovarian malignancy is 64% and that of the malignant Ovarian tumor is 36%. The incidence of the ovarian tumor was found in all age groups. In the present study the youngest patient was 17 years old and that of the oldest patient was 92 years. Total of 55 women were premenopausal and 45 were postmenopausal. 16 women were between the age group of 41 to 50 years and 17 women were between the age group of 51 to 60 years. Mean age of patients with benign tumors was  $48.28 \pm 18.65$  while in patients with malignant tumors it was  $48.22 \pm 14.60$  years. The average age for benign tumor was 33.1 years and for malignant tumours; it was 44.6 years according to study conducted by Parker et al.<sup>11</sup>

In our study, the proportion of patients in malignant ovarian tumour group as compared to benign ovarian tumour group was higher for the symptoms of dyspepsia, distension, pain lower abdomen and loss of appetite. However, the difference between the two groups was statistically significant only for distension (0.028) and loss of appetite ( $p=0.019$ ). The proportion of patients in benign group as compared to malignant group was higher for symptoms of menstrual abnormality ( $p=0.201$ ) and the difference is not statistically significant. The majority of women with epithelial ovarian cancer have vague and non-specific symptoms like dull aching dragging sensation. If a pelvic mass is compressing the bladder or the rectum; there may increase frequency of micturition or constipation respectively. Also abdominal distention, bloating, respiratory difficulty, constipation, nausea, anorexia and early satiety may be due to advanced state of the disease. In our study as compared to benign group, the proportion of subjects with clinical signs such as ascites and abdominopelvic mass was higher in the malignant group. The difference was also found to be significant statistically for the sign ascites ( $p<0.05$ ) as well as for abdominopelvic mass ( $p<0.05$ ).

Vora and Bhargava studied 330 ovarian neoplasms abdominopelvic lump was the symptom in 50 % and pain abdomen was the in 20% cases.<sup>12</sup> In 1981, Similarly Shikdar et al. reported in detail 149 cases (23.46%) of malignant ovarian tumours out of 635 cases from Calcutta. The preponderance of the malignant ovarian tumours was in the age group 41-50 years. Abdominopelvic lump (52.1%) and pain abdomen (40.1%) were the commonest presentation.<sup>12</sup>

In our study, it was found that RMI score is a good predictor having both high sensitivities (80.5%) as well as specificity (85.9%), positive predictive value (76.3%) and a very good negative predictive value (88.7%). Overall the diagnostic accuracy is excellent (84%). In 1990, Jacob I, et al. found that the sensitivity to be 85% and specificity to be 97%.<sup>9</sup>

In our study while comparing the predictive value of post-menopausal status with other parameters taken in study, it was observed that for subjects with CA125 $\geq$ 35 IU/ml in pre-menopausal group, only 42% had malignant pathology whereas among postmenopausal subjects with CA125  $\geq$ 35 IU/ml, 95% cases had malignant pathology thus the positive predictive value of CA-125 for malignancy was more than 1.3 times in post-menopausal group as compared to pre-menopausal group. In post-menopausal group CA-125 showed high negative predictive value for benign cases (69.2%) as compared to pre-menopausal group. In post-menopausal group, the proportion of true malignant tumours and true benign tumour was higher both in cases CA125 $\geq$ 35 and CA-125 <35 subjects respectively.

In our study, positive predictive value of USG was only 38% for pre-menopausal and 65.3% for post-menopausal subjects, thereby showing the test to be having about 2 times more positive predictive value among post-menopausal subjects as compared to premenopausal subject. There was a little increase in negative predictive value in post-menopausal group (84.2%) as compared to pre-menopausal group (79%). In 1997, Ferrazi E et al did a transvaginal ultra-sonographic characterization of the ovarian masses using wall thickness, septations, vegetations and echogenic patterns of the ovarian neoplasms. They concluded that differentiation of benign from malignant masses cannot be obtained by sonographic imaging alone.<sup>13</sup>

In our study there was a fair agreement between RMI score and USG score. 30 out of 38 cases having RMI score >200 had USG score >3, however, same extent of agreement was not observed for RMI score <200 where 40 out of 62 (45%) cases had USG score <3. Overall an agreement of 62% was observed between the two techniques. On evaluating the data statistically, the extent of agreement between two groups was found to be fair (K=0.406) with a very high significance level (p<0.001), thus implying that the variability/disagreement between two techniques is not merely by chance, rather it is significant statistically too (p<0.001).

In our study there was a good agreement between RMI score and CA 125 score. Amongst patient with RMI score >200, CA125 score was  $\geq$ 35 IU/ml in 91.7% patients. 80.7% subjects having RMI score had CA125 score <35IU/ml. Overall an agreement of 82% was observed between the two techniques. On evaluating the data statistically, the extent of agreement between two groups was found to be moderate (K=0.459) with a very high significance level (p<0.001).

On evaluation of agreement between CA-125 and USG Score, a fair agreement was observed between the two. In patients with CA-125 >35IU/ml, USG Score >3 was observed in only 64.9% while in subjects with CA-125 score <35IU/ml, only 65% had USG score <3. Overall an agreement was observed in only 65% cases. On statistical

evaluation, the extent of agreement between two techniques was observed to be fair ( $\kappa$ =0.296) which was not so significant statistically, thus implying that the results of agreement between two techniques are subject to chance variability.

Holbert et al, screened 478 postmenopausal women. He used transvaginal ultrasound and if found to be positive used CA-125 as a level II screen. Of the 33 positive screen women; 11 were found to have ovarian cancer.<sup>14</sup> Buys et al. in 2005 found a positive predictive value of 4 % for CA- 125 alone and 26.5 % for abnormal CA 125 combined with transvaginal sonography.<sup>15</sup>

In the present study all the cases detected to be malignant and those who were detected to be likely malignant on laparoscopy were subjected to laparotomy. Laparoscopy was reserved for patients who had a high likelihood of benign pathology on the basis of RMI Score. 18.4% women with RMI Score >200, who otherwise had benign pathology underwent laparotomy while 25% of patients with USG Score of 3 found to be having benign pathology on confirmation underwent laparotomy. 15 patients thought to be benign by CA-125 level and also confirmed to be having benign pathology underwent laparotomy whereas 14 patients in USG and 22 in RMI group underwent laparotomy.

There was one subject detected to be having benign ovarian by CA-125 but confirmed to be malignant otherwise underwent laparotomy while 4 cases detected to be negative for malignancy by RMI Score but confirmed to be malignant otherwise too underwent laparotomy.

In our study amongst benign tumors; Endometrial cyst (26.5%) was most common tumor followed by serous cystadenoma (17.1%) and mucinous cystadenoma (15.6%). Struma ovarii was among the least common (1.5). Serous cystadenocarcinoma was the most common (58.3%) amongst the malignant group followed by mucinous cystadenocarcinoma (16.6%). Also clear cell carcinoma, adult granulosa cell tumor and malignant Brenner's tumor were 5.5 % each. In 1969, Vora and Bhargava studied 330 ovarian neoplasms; 81% were benign and 19% were malignant.<sup>12</sup>

Ramachandran et al, in 1971 recorded 903 ovarian neoplasms in Thiruvanthapuram. 622 (68.98%) were benign and 281 were malignant. Serous cystadenomas were 181 (20.03%), mucinous cystadenomas were 165 (18.27%), cystic teratomas were 157 (17.95%), and serous cystadenocarcinomas were 22 (2.44%). There were 36 (3.99 %) cases of dysgerminoma and 25 (2.77%) of granulosa cell tumors.<sup>16</sup>

## CONCLUSION

In our study the proportion of women in malignant tumour group with RMI >200 was significantly higher.

Sensitivity of RMI Score in the pre-menopausal women was 70.5% and in post-menopausal women was 89.4%. Specificity of RMI Score in the pre-menopausal women was 86.8% and in post-menopausal women was 84.6%. The positive predictive value in the pre-menopausal women was 70.5% and in post-menopausal women was 80.9%. The negative predictive value in the pre-menopausal women was 86.8% and in post-menopausal women was 91.4%. Diagnostic accuracy in case of pre-menopausal women is 81.8% and 86.6% for postmenopausal women. It shows that there is a substantial role of RMI Score in prediction of ovarian malignancy. RMI Score helps in identifying the patients who require Staging Laparotomy and hence referral to Gynaecologic Oncologist.

*Funding: No funding sources*

*Conflict of interest: None declared*

*Ethical approval: The study was approved by the Institutional Ethics Committee*

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**Cite this article as:** Rao PS, Bala R, Prajwal S. Risk of malignancy index in ovarian tumour for predicting ovarian malignancy by using jacob's score. *Int J Reprod Contracept Obstet Gynecol* 2017;6:1318-25.