

Risk of Malignancy Index in the Preoperative Evaluation of Patients with Adnexal Masses among Women of Perimenopausal and Postmenopausal Age Group

Daibi Guin¹, Pallab Kumar Mistri², Bandana Biswas³

¹Contractual Medical Officer, Basirhat Superspeciality Hospital, Basirhat, West Bengal, India.

²Associate Professor, Dept. Of Obstetrics & Gynaecology, Medical College, 88, College Street, Kolkata-700073

³Professor, Dept. Of Obstetrics & Gynaecology, Medical College, 88, College Street, Kolkata-700073

Corresponding Author: Pallab Kumar Mistri

Abstract

INTRODUCTION: In some ovarian cancer especially in early stage, risk of malignancy index (RMI) is proposed for clinical use and is found to yield better result indiscriminating between benign and malignant ovarian tumours than any single test of morphologic Ultrasound scores, CA 125, or menopausal status.

MATERIALS AND METHODS: 100 patients were taken up into 2 groups of 50 each depending on RMI, group A having patients with RMI>200 (n=50), group B having patients with RMI<200 (n=50).

RESULTS: Analysis shows that there is 1.6 times more chance of a tumour being malignant in postmenopausal women than in peri-menopausal women with adnexal mass. There is statistically significant increased incidence of malignancy in postmenopausal women (p value= 0.0265). The study finds the best cut-off value for RMI is at >230.

DISCUSSION: Comparison of all parameters, CA-125, USG score and RMI to predict malignancy show, CA-125 has the highest sensitivity and lowest specificity. The ROC curves of the 3 tests and AUC under these curves show, the highest AUC was observed with RMI and lowest with USG score. So performance of RMI is the best among all parameters to predict malignancy in adnexal masses.

Key Words: Risk of malignancy index(RMI), Ovarian malignancy, CA-125, USG Score

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I. Introduction

Ovarian cancer is the responsible for fifth leading cause of cancer related death.¹ Worldwide each year, more than 225,000 women are diagnosed and 140,000 women die from the disease.² A woman's risk at birth of having ovarian cancer at some point in her lifetime is 1-1.5% and that of dying from ovarian cancer is almost 0.5%. Of these 90-95% are ovarian epithelial cancers including the more indolent low malignant potential (borderline) tumors.³ Numerous environmental, reproductive and genetic factors influence development of epithelial ovarian cancer. CA 125 is an antigenic determinant on a high-molecular-weight glycoprotein recognized by a monoclonal antibody (OC 125). The full-length CA 125 glycoprotein contains more than 11,000 amino acids in its proteinaceous core and has been termed Muc16 to reflect the mucin like nature of the antigen and is now identified as a new member of the protein family of mucins.⁴ The reference range of CA 125 is 0-35 units/mL (0-35 kU/L).. However, owing to the lack of sensitivity and specificity, elevations in single or sequential CA 125 levels alone are not recommended for ovarian cancer screening or in the initial diagnosis of ovarian cancer.^{5,6} USG imaging plays a crucial role in the initial detection of adnexal lesions and morphologic features at USG suggestive of ovarian malignancy include an irregular solid mass, an irregular multilocular cystic mass, solid components or papillary vegetations on the cyst wall, high flow within solid components on colour Doppler images, ascites, peritoneal nodules, and other evidence of metastases.^{7,8,9}

In early stage cancer, correct preoperative differentiation between benign versus malignant tumors is difficult for an appropriate surgical treatment. Either USG study or CA 125 determination has its own limitation in diagnosis of ovarian tumours. Many authors have attempted to combine these tests together to yield a better diagnostic performance. Risk of malignancy index (RMI) is proposed for clinical use and is found to yield better result indiscriminating between benign and malignant ovarian tumours than any single test of morphologic USG scores, CA 125, or menopausal status. The aims and objectives of this study was to assess the ability of the risk of malignancy index (RMI) based on a serum CA125 level, ultrasound findings and menopausal status, to discriminate benign from malignant adnexal masses preoperatively among women of peri and postmenopausal age group.

II. Materials And Methods

The prospective observational study was carried out from March 2015 to February 2016 in the Department of Obstetrics and Gynaecology in association with the Department of Radiology, Medical College and Hospital, Kolkata, after approval from Hospital Ethics Committee. Women with ovarian masses, who were scheduled to have elective exploratory laparotomy or laparoscopy at the Department of Obstetrics and Gynaecology, Medical College and Hospital, Kolkata, were included in the study. All women under study gave their consent prior to this. Perimenopausal and postmenopausal women of age group more than 40 years presenting with adnexal masses were included for our study^{11,13}. Women with adnexal masses less than 40 years of age, already diagnosed of ovarian malignancy and received chemotherapy were excluded. Initially 113 patients were selected but 7 patients of them did not meet the inclusion criteria (3 of them had recurrent ovarian epithelial cancer, 2 had broad ligament fibroid, 1 had sub-serosal fibroid, 1 had retro-peritoneal sarcoma) and 6 patients opted out of the study. Finally, 100 patients were included in the study and divided into 2 groups of 50 each to depending on RMI. So, data from 100 patients were available for analysis; group A having patients with RMI>200 (n=50), group B having patients with RMI<200 (n=50). After they went laparotomy, their histopathology reports were examined. For all patients admitted with abdominal lump, after history taking and proper examination RMI was calculated after collecting all the parameters such as menopausal status, serum CA-125 level, USG Score. For study purpose Serum CA 125 (by radioimmunoassay) and the ultrasound examination (using a 3.5-MHz abdominal convex transducer or 7.5-MHz vaginal probe) were performed at the time of preoperative laboratory assessment. After pre-anaesthetic check-up patients underwent laparotomy and specimens were sent for HPE. Histological diagnosis was considered as gold standard.

Perimenopause begins with the onset of clinical features of approaching menopause and ends 12 months after the final menstrual period. In this study women above 40 years of age who were not post menopausal were considered as perimenopausal. Postmenopausal status was defined as more than 1 year of amenorrhea or an age of more than 50 years in women who had had a hysterectomy. For RMI calculation each woman was given a menopausal score (M). If they were postmenopausal then, menopausal score, M=4, otherwise in perimenopausal women M=1, were considered. Ultrasound features, noted for scoring were multilocular cyst, presence of solid areas, bilaterality of lesions, presence of ascites, presence of intra-abdominal metastasis. USG score was calculated as, U=1 (When no or 1 abnormality was present) or U=4 (When 2 or more abnormalities were present)

$$\text{RMI score} = M \times U \times \text{Serum CA125 level in U/ml}$$

III. Results

100 patients were taken up into 2 groups of 50 each to depending on RMI. So, data from 100 patients were available for analysis; group A having patients with RMI>200 (n=50), group B having patients with RMI<200 (n=50). Observations were tabulated in excel sheet and analyzed. Continuous data were expressed as mean \pm SEM. Discrete categorical data were presented as number of patients [*n* (%)] and median value. Comparisons of continuous data were performed using the unpaired *t* test. Categorical data were analyzed with contingency tables using Fisher's exact test. Sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were calculated. Statistical tests were considered significant when *p* value<0.05. All analyses were conducted using GraphPad InStat version 3.06, 32 bit for Windows. Receiver Operating Characteristics (ROC) curves were drawn and Area Under Curve (AUC) using MedCalc version 16.8.4 for Windows.

Table 1 shows that the two groups were comparable in terms of age, parity, height as per distribution (*p* value 0.263, 0.149 and 0.795 respectively) but there was difference in weight and mean BMI (*p*=0.004 and 0.003).

Table 2 show that, 55 patients were post-menopausal, among them 63.63% (n=35) had malignant tumours and 41.81% (n=20) had benign lesions, among 45 peri-menopausal women, 40% (n=18) had malignant masses, and 60% (n=27) had benign pathology. Analysis shows that there is 1.6 times more chance of a tumour being malignant in postmenopausal women than in peri-menopausal women with adnexal mass. There is statistically significant increased incidence of malignancy in postmenopausal women (*p* value= 0.0265).

Table 3 shows distribution of serum CA-125 level in benign and malignant masses. The mean serum CA-125 level was 731.255 \pm 101.010 U/ml in patients with malignancy, while patients with benign mass had a mean serum CA-125 level 40.169 \pm 6.298 U/ml. There was statistically significant difference in serum CA-125 level in patients with malignant and benign mass (*p*=0.003). It is also seen that, serum CA-125 level >35U/ml was found in 64 patients, among which malignancy was present in 76.56% (n=49) and 23.43% (n=15) were benign lesions, serum CA-125 level <35U/ml was observed in 36 patients, among which malignancy was present in 11.11% (n=4) and 88.88% (n=32) were benign lesions. Using serum CA-125>35U/ml as a predictive marker of malignancy in adnexal mass results in Sensitivity of 92.45% (95% CI= 81.78% - 97.9%), Specificity of 68.09% (95% CI= 52.84% - 80.9%), PPV of 76.56% (95% CI= 64.32% - 86.23%), NPV of 88.89% (95%

CI= 73.96% - 96.89%). It is statistically significant (p value <0.0001). Table 4 analyses criterion values and coordinates of the ROC curve and analysing it we see the best cut-off value for serum CA-125 is at >35.66 U/ml.

USG parameters are analysed in table 5 individually first, then compared with each other and finally USG score is analysed for efficacy to predict malignancy in adnexal mass. Mass of 53 patients showed presence of multilocularity detected sonographically, of which 67.92% (n=36) were malignant and 32.07% (n=17) were benign. In 47 patients adnexal mass was unilocular, among them 36.17% (n=17) had malignant mass and 63.82% (n=30) had benign mass proven histologically. Using presence of multilocularity as a predictive marker of malignancy in adnexal mass results in Sensitivity of 67.92% (95% CI= 53.73% - 80.09%), Specificity of 63.83% (95% CI= 48.50% - 77.33%), PPV of 67.92% (95% CI= 53.73% - 80.09%), NPV of 63.83% (95% CI= 48.50% - 77.33%). It is statistically significant (p value = 0.0024). It was also seen that mass of 68 patients showed presence of solid areas detected sonographically, of which 70.58% (n=48) were malignant and 29.41% (n=20) were benign. In 32 patients adnexal mass was having no solid area, among them 15.62% (n=5) had malignant mass and 84.37% (n=27) had benign mass proven histologically. Using presence of solid areas as a predictive marker of malignancy in adnexal mass results in Sensitivity of 90.57% (95% CI= 79.35% - 96.86%), Specificity of 57.45% (95% CI= 42.19% - 71.78%), PPV of 70.59% (95% CI= 58.27% - 81.05%), NPV of 84.38% (95% CI= 67.25% - 94.73%). It is statistically significant (p value < 0.0001). 36 patients showed presence of bilaterality detected sonographically, of which 75% (n=27) were malignant and 25% (n=9) were benign. In 64 patients adnexal mass was unilateral, among them 40.62% (n=26) had malignant mass and 59.37% (n=38) had benign mass proven histologically. Using presence of bilaterality as a predictive marker of malignancy in adnexal mass results in Sensitivity of 50.94% (95% CI= 36.83% - 64.98%), Specificity of 80.85% (95% CI= 66.73% - 90.86%), PPV of 75.00% (95% CI= 57.78% - 87.89%), NPV of 59.38% (95% CI= 46.35% - 71.44%). It is statistically significant (p value = 0.0016). 42 patients showed presence of ascites detected sonographically, of which 100% (n=42) were malignant and none (n=0) was benign. In 58 patients no ascites was there, among them 18.96% (n=11) had malignant mass and 81.03% (n=47) had benign mass proven histologically. Using presence of ascites as a predictive marker of malignancy in adnexal mass results in Sensitivity of 79.25% (95% CI= 65.93% - 89.17%), Specificity of 100% (95% CI= 92.45% - 100%), PPV of 100% (95% CI= 91.59% - 100%), NPV of 81.03% (95% CI= 68.6% - 90.12%). It is statistically significant (p value < 0.0001). 11 patients had presence of intra-abdominal metastasis detected sonographically, of which 100% (n=11) were malignant and none (n=0) was benign. In 89 patients no metastasis was there, among them 47.19% (n=42) had malignant mass and 52.81% (n=47) had benign mass proven histologically. Using presence of metastasis as a predictive marker of malignancy in adnexal mass results in Sensitivity of 20.75% (95% CI= 10.83% - 34.07%), Specificity of 100% (95% CI= 92.45% - 100%), PPV of 100% (95% CI= 71.52% - 100%), NPV of 52.81% (95% CI= 41.96% - 63.46%). It is statistically significant (p value = 0.0007). 57 patients had USG score of 4, of which 84.21% (n=48) were malignant and 15.78% (n=9) was benign. In 43 patients USG score was 1, among them 11.62% (n=5) had malignant mass and 88.37% (n=38) had benign mass proven histologically. Using USG score as a predictive marker of malignancy in adnexal mass results in Sensitivity of 90.57% (95% CI= 79.35% - 96.86%), Specificity of 80.85% (95% CI= 66.73% - 90.86%), PPV of 84.21% (95% CI= 72.12% - 92.51%), NPV of 88.37% (95% CI= 74.91% - 96.11%). It is statistically significant (p value < 0.0001). Highest sensitivity was observed with presence of solid areas and highest specificity with both presence of ascites and metastasis, among individual parameters. Overall the best diagnostic performance was obtained with USG score.

Table 6 shows distribution of RMI in benign and malignant masses. The mean RMI was 731.255 ± 101.010 U/ml in patients with malignancy, while patients with benign mass had a mean RMI 40.169 ± 6.298 U/ml. There was statistically significant difference in RMI in patients with malignant and benign mass (p=0.003). It is also seen that, RMI >200 was found in 50 patients, among which malignancy was present in 96% (n=48) and 4% (n=2) were benign lesions, RMI <200 was observed in 50 patients, among which malignancy was present in 10% (n=5) and 90% (n=45) were benign lesions Table 7 shows criterion values and coordinates of the ROC curve and analysing it we see the best cut-off value for RMI is at >230. Using RMI >200 as a predictive marker of malignancy in adnexal mass results in Sensitivity of 90.57% (95% CI= 79.35% - 96.86%), Specificity of 95.74% (95% CI= 85.47% - 99.48%), PPV of 96.00% (95% CI= 86.29% - 99.51%), NPV of 90.00% (95% CI= 78.21% - 96.67%). It is statistically significant (p value <0.0001).

Table 8 compares CA-125, USG score and RMI to predict malignancy. Though serum CA-125 has the highest sensitivity and lowest specificity, highest specificity, PPV and NPV were associated with RMI. Highest AUC was observed with RMI and lowest with USG score. So performance of RMI is the best among all parameters to predict malignancy in adnexal masses.

Out of 53 malignant tumours, 43 were Serous Cystadenocarcinoma, 9 were Mucinous Cystadenocarcinoma, 2 were Endometrioid carcinoma, 1 each Clear cell carcinoma and Krukenberg tumour.

Among the benign tumours. Of them 26 were Serous cystadenoma, 14 were Endometrioma, 4 were Mucinous cystadenoma, 1 each Seromucinous cystadenoma, Fibroma and Brenner tumour.

In 50 patients with adnexal masses having RMI > 200, 2 tumour were benign, both of which were Endometrioma, so while using RMI as a predictor of malignancy, all false positive reports were due to Endometrioma.

In 50 patients with adnexal masses who have RMI < 200, malignancy was present in 5 cases, false negative reports were due to Serous Cystadenocarcinoma (n=3), Mucinous Cystadenocarcinoma (n=1), Clear cell carcinoma (n=1).

IV. Discussion

In our study, it is observed that that there is 1.6 times more chance of a tumour being malignant in postmenopausal women than in peri-menopausal women with adnexal mass. There is statistically significant increased incidence of malignancy in postmenopausal women (p value= 0.0265). There were significantly more malignant tumours in the postmenopausal group (P=0.000) in the study by Ashrafgangooei T et al, in 2011.¹⁰

In our study the best cut-off value for serum CA-125 is at >35.66 U/ml. Using serum CA-125>35U/ml as a predictive marker of malignancy in adnexal mass results in Sensitivity of 92.45% (95% CI= 81.78% - 97.9%), Specificity of 68.09% (95% CI= 52.84% - 80.9%), PPV of 76.56% (95% CI= 64.32% - 86.23%), NPV of 88.89% (95% CI= 73.96% - 96.89%). It is statistically significant (p value <0.0001). ROC curve of diagnostic performance of serum CA-125 analyses AUC and shows AUC=0.897. The study by Alanbay I et al (2011) showed, Receiver Operator Characteristic area under the curves for serum CA 125 was 0.548.¹¹

In this study while using USG score individually as a predictive marker of malignancy in adnexal mass results in Sensitivity of 90.57% (95% CI= 79.35% - 96.86%), Specificity of 80.85% (95% CI= 66.73% - 90.86%), PPV of 84.21% (95% CI= 72.12% - 92.51%), NPV of 88.37% (95% CI= 74.91% - 96.11%). It is statistically significant (p value < 0.0001). ROC curve of diagnostic performance of USG score analyses AUC and shows AUC=0.857. In the study of Park JW et al (2013), receiver operating characteristic (ROC) curves of ultrasound score showed areas under the curves of 0.784.¹³

This study finds the best cut-off value for RMI is at >230. ROC curve of diagnostic performance of RMI analyses AUC and shows AUC=0.959. Using RMI >200 as a predictive marker of malignancy in adnexal mass results in Sensitivity of 90.57% (95% CI= 79.35% - 96.86%), Specificity of 95.74% (95% CI= 85.47% - 99.48%), PPV of 96.00% (95% CI= 86.29% - 99.51%), NPV of 90.00% (95% CI= 78.21% - 96.67%). It is statistically significant (p value <0.0001). Comparison of all parameters, CA-125, USG score and RMI to predict malignancy show, CA-125 has the highest sensitivity and lowest specificity. The highest specificity, PPV and NPV were associated with RMI. The ROC curves of the 3 tests and AUC under these curves show, the highest AUC was observed with RMI and lowest with USG score. So performance of RMI is the best among all parameters to predict malignancy in adnexal masses. Hakansson F et al used RMI \geq 200 and noticed sensitivity and specificity were 92% and 82%, respectively. Corresponding positive and negative predictive values were 62% and 97%.¹²

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TABLES:

Table.1. Distribution Of Patients According To Age (years), Parity, Weight (kg), Height (cm), BMI (kg/m²) In Group A And Group B

Mean of Parameters	Group A (n = 50)	Group B (n = 50)	p value
Age (years)	53.98	51.82	0.263(NS)
Parity	3.38	2.94	0.149(NS)
Weight (kg)	54.38	59.44	0.004(S)
Height (cm)	156.34	156.62	0.795(NS)
BMI(Kg/m ²)	22.199	23.93	0.003(S)

Table 2: Menopausal Status and Malignancy

Parameters	Malignant	Benign	Total
Postmenopausal	n=35(63.63%)	n=20 (41.81%)	55
Perimenopausal	n=18 (40%)	n=27 (60%)	45
Total	53	47	100

Table 3: Distribution of CA-125 Level

	Malignant (n=53)	Benign (n=47)	p-value
Mean±SEM	731.255±101.01	40.169±6.298	p-value < 0.0001
CA-125>35 (As a screening test)	n=49 TP=76.56%	n=15 FP=23.43%	
CA-125<35 (As a screening test)	n=4 FN=11.11%	n=32 TN=88.88%	

Table 4: Criterion Values And Coordinates Of ROC Curve Of CA-125

Criterion	Sensitivity	95% CI	Specificity	95% CI	+LR	-LR
≥4.92	100.00	93.3 - 100.0	0.00	0.0 - 7.5	1.00	
>4.92	98.11	89.9 - 100.0	0.00	0.0 - 7.5	0.98	
>5.5	98.11	89.9 - 100.0	2.13	0.05 - 11.3	1.00	0.89
>5.6	96.23	87.0 - 99.5	2.13	0.05 - 11.3	0.98	1.77
>6	94.34	84.3 - 98.8	6.38	1.3 - 17.5	1.01	0.89
>15.1	94.34	84.3 - 98.8	38.30	24.5 - 53.6	1.53	0.15
>15.5	92.45	81.8 - 97.9	38.30	24.5 - 53.6	1.50	0.20
>35.66	92.45	81.8 - 97.9	70.21	55.1 - 82.7	3.10	0.11
>40	90.57	79.3 - 96.9	72.34	57.4 - 84.4	3.27	0.13
>44	90.57	79.3 - 96.9	74.47	59.7 - 86.1	3.55	0.13
>45	86.79	74.7 - 94.5	74.47	59.7 - 86.1	3.40	0.18
>50	86.79	74.7 - 94.5	76.60	62.0 - 87.7	3.71	0.17
>56	84.91	72.4 - 93.3	78.72	64.3 - 89.3	3.99	0.19
>57.5	84.91	72.4 - 93.3	80.85	66.7 - 90.9	4.43	0.19
>82.6	83.02	70.2 - 91.9	80.85	66.7 - 90.9	4.34	0.21
>87	83.02	70.2 - 91.9	87.23	74.3 - 95.2	6.50	0.19
>88.5	81.13	68.0 - 90.6	87.23	74.3 - 95.2	6.36	0.22
>89.9	81.13	68.0 - 90.6	89.36	76.9 - 96.5	7.63	0.21
>100.6	73.58	59.7 - 84.7	89.36	76.9 - 96.5	6.92	0.30
>105.6	73.58	59.7 - 84.7	95.74	85.5 - 99.5	17.29	0.28
>116.3	71.70	57.7 - 83.2	95.74	85.5 - 99.5	16.85	0.30
>126.7	71.70	57.7 - 83.2	97.87	88.7 - 99.9	33.70	0.29
>234.4	64.15	49.8 - 76.9	97.87	88.7 - 99.9	30.15	0.37
>235.5	64.15	49.8 - 76.9	100.00	92.5 - 100.0		0.36
>2981.87	0.00	0.0 - 6.7	100.00	92.5 - 100.0		1.00

Table 5: USG Score parameters

Parameters	Malignant (n=53)	Benign (n=47)	p-value
Multilocularity Present	n=36 TP=67.92%	n=17 FP=32.07%	0.0024 (S)
Multilocularity Absent	n=17 FP=36.17%	n=30 TN=63.82%	
Solid area present	n=48 TP=70.58%	n=20 FP=29.41%	<0.0001 (S)
Solid area absent	n=5 FN=15.62%	n=27 TN=84.37%	
Bilateral	n=27	n=9	0.0016 (S)

	TP=75%	FP=25%	
Unilateral	n=26 FN=40.62%	n=38 TN=59.37%	
Ascites present	n=42 TP=100%	n=0 FP=0%	<0.0001 (S)
Ascites absent	n=11 FN=18.96%	n=47 TN=81.03%	
Metastasis present	n=11 TP=100%)	n=0 FP=0%	0.0007 (S)
Metastasis absent	n=42 FN=47.19%)	n=47 TN=52.18%	
USG score=4	n=48 TP=84.21%	n=9 FP=15.78%	<0.0001 (S)
USG score=1	n=5 FN=11.62%	n=38 TN=88.37%	

Table 6: RMI Distribution

	Malignant (n=53)	Benign (n=47)	p-value
Mean±SEM	7520.072±1110.3	95.218±19.641	p-value < 0.0001
RMI>200 (as a screening test for malignancy)	n=48 TP=96%	n=2 FP=4%	
RMI<200 (as a screening test for malignancy)	n=5 FN=10%	n=45 TN=90%	

Table 7: Criterion Values And Coordinates Of The ROC Curve Of RMI

Criterion	Sensitivity	95% CI	Specificity	95% CI	+LR	-LR
≥10.1	100.00	93.3 - 100.0	0.00	0.0 - 7.5	1.00	
>60.4	100.00	93.3 - 100.0	46.81	32.1 - 61.9	1.88	0.00
>62	98.11	89.9 - 100.0	46.81	32.1 - 61.9	1.84	0.040
>69.2	98.11	89.9 - 100.0	51.06	36.1 - 65.9	2.00	0.037
>78.72	96.23	87.0 - 99.5	51.06	36.1 - 65.9	1.97	0.074
>89.9	96.23	87.0 - 99.5	65.96	50.7 - 79.1	2.83	0.057
>92.8	94.34	84.3 - 98.8	65.96	50.7 - 79.1	2.77	0.086
>96	92.45	81.8 - 97.9	70.21	55.1 - 82.7	3.10	0.11
>105.6	92.45	81.8 - 97.9	76.60	62.0 - 87.7	3.95	0.099
>116.3	90.57	79.3 - 96.9	76.60	62.0 - 87.7	3.87	0.12
>230	90.57	79.3 - 96.9	97.87	88.7 - 99.9	42.57	0.096
>937.6	67.92	53.7 - 80.1	97.87	88.7 - 99.9	31.92	0.33
>942	67.92	53.7 - 80.1	100.00	92.5 - 100.0		0.32
>26862.4	0.00	0.0 - 6.7	100.00	92.5 - 100.0		1.00

Table 8: Comparison Of CA-125, USG Score And RMI

Parameters	AUC	Sensitivity	Specificity	PPV	NPV	p value
CA-125≥35	0.897	92.45%	68.09%	76.56%	88.89%	<0.0001 (S)
USG score=4	0.857	90.57%	80.85%	84.21%	88.37%	<0.0001 (S)
RMI≥200	0.959	90.57%	95.74%	96.00%	90.00%	<0.0001 (S)

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