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RESEARCH ARTICLE

USE OF RISK OF MALIGNANCY INDEX IN PREOPERATIVE EVALUATION OF ADNEXAL MASSES

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ABSTRACT

Background: Ovarian cancer is responsible for the most deaths in the gynaecological sphere. It is the second most common gynaecological malignancy in developed countries, and is the leading cause of cancer deaths among women. It causes more mortality than all other gynaecological malignancies together. The purpose of this study was to evaluate the accuracy of the risk of malignancy index (RMI) which combines serum CA125 levels, ultrasound score, and menopausal state in discriminating between benign and malignant adnexal masses in a selected population of apparently early lesions.

Methods: A prospective cohort study was conducted for a period of one year of 120 women with an adnexal mass. The serum CA125 level, the ultrasound findings and menopausal status were noted. Risk of malignancy score based on product of ultrasound findings, menopausal status and CA-125 level was calculated.

Results: Risk of malignancy index (RMI) proved to be the most sensitive index in depicting malignancy. The mean levels of RMI were much higher among the malignant group. RMI scores were divided in to various groups and sensitivity, specificity, PPV and NPV for each group was tested. RMI score >200 showed the best sensitivity (91.89%) with specificity, PPV and NPV of 83.33%, 97% 62.50% respectively. RMI>200 was 90.69% accurate in differentiating benign and malignant adnexal masses preoperatively. This was much higher than any of the other parameters used alone. However, RMI was not able to diagnose Mucinous carcinomas because of the lower levels of CA 125 found this type of malignancy.

Conclusion: RMI is a reliable tool in differentiating benign from malignant adnexal masses. It is simple, easy to use and cost effective. However it's predictive accuracy was less for mucinous as compared to other ovarian cancers.

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INTRODUCTION

The ovary is an organ with a complex embryology and steroidogenesis, which is always changing, undergoing more structural changes than any other organ. It has a default (pre-established) development, for a given period of time, between puberty and menopause, which is genetically determined. Woman's biological clock runs on the interdependence of secreted hormones (which regulates the reproductive function) and their receptors, relationship that transforms the ovary in to a target organ. In the first part of a woman's reproductive life the ovary is predisposed mainly for developing active inflammatory phenomena, starting with pre-menopause and menopause, it becomes the target of neoplastic processes. The ovarian pathology is currently among the widest and most complex problems in modern gynaecology mainly through ovarian tumors. Despite its small size, ovary is an organ that requires the attention of several specialties like gynaecology, endocrinology and pathology. Ovarian tumor pathology is a medical problem which frequently echoes in the family and social sphere. Advancements in science and modern diagnostic methods made possible thorough investigation of this organ but there are still unsolved questions. An adnexal mass is a lump in tissue of the adnexa of uterus (structures closely related structurally and functionally to the uterus such as the ovaries, fallopian tubes, or any of the surrounding connective tissue). Adnexal masses can be benign or cancerous, and they can be categorized as simple or complex. One of the most important factors used to determine the clinical suspicion of malignancy of an adnexal mass is the sonographic appearance of the mass. (Curtin, 1994) Indications that the mass is at a higher risk of being malignant include: presence of loculations, nodules, papillary structures, septations, size greater than 10 cm. (Koonings *et al*., 1989) The normal functioning ovary produces a follicular cyst 6-7 times each year. In most cases, these functional cysts are self-limiting and resolve within the duration of a normal menstrual cycle. In rare situations, a cyst persists longer or becomes enlarged. At this point, it represents a pathological adnexal mass. Adnexal masses present a

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diagnostic dilemma; the differential diagnosis is extensive, and most masses are benign. (Yuen *et al*., 1997) However, without histopathologic tissue diagnosis, a definitive diagnosis is generally precluded. Physicians must evaluate the likelihood of concerning pathologic process using clinical and radiologic information and balance the risk of surgical intervention for a benign versus malignant process. As the adnexa are located deep in the pelvis, masses may be palpated with a standard gynecologic examination. Findings such as nodularity, irregular adnexal contour, or fixed position are suggestive of malignancy. However, other factors, such as obesity and size of mass, may limit the accuracy of physical examination. The main problem in the clinical management of adnexal masses is the risk of malignancy. Because of this risk of malignancy, adnexal masses have to be assessed carefully prior to surgery. Treatment of a malignant mass is entirely different from that of a benign mass. Despite the progress in cancer therapy, ovarian cancer mortality has remained virtually unchanged over the past two decades. This is attributed to the difficulties in early diagnosis and therefore, ovarian cancer has the highest mortality rate of all the gynaecological cancers. (Kristensen and Trope, 1997) The overall survival rate of ovarian cancer is about 50% over a 5-year period, and this is largely dependent upon the stage of the disease at the time of diagnosis. However, early diagnosis of this cancer results in a 5-year survival rate of about 80%. (Kristensen and Trope, 1997) Regular pelvic examinations and CA-125 measurements followed by radiological diagnosis on an individualized basis have been the current practice for detection of this enigmatic condition. However, neither an elevated serum CA-125 level, nor the presence of an ovarian cyst identified by clinical examination and ultrasonography, accurately predicts the occurrence of an ovarian malignancy. (Van Nagell *et al*., 2000) Keeping in view the above facts, the present study was conducted to evaluate the risk of malignancy index to identify the probability of malignant pelvic masses by incorporating serum CA 125 levels, ultrasound morphology and menopausal status in a selected population of apparently early lesions.

MATERIALS AND METHODS

The present study was conducted for a period of one year starting from October 2014 to September 2015 in the Postgraduate Department of Obstetrics and Gynaecology SMGS Hospital, GMC Jammu after obtaining approval by the hospital ethical committee. The aim of the study was explained appropriately and informed written consent was obtained. Women who were already a diagnosed case of malignancy were excluded from the study. 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. Risk of malignancy score based on product of ultrasound findings, menopausal status and CA-125 level was calculated by the following formula

$$RMI = U \times M \times CA\text{-}125$$

Where,

RMI - Risk of malignancy Index (RMI was the first diagnostic model to combine demographic, sonographic and biochemical data in assessment of patients with pelvic masses. RMI was first developed by Jacobs *et al*. in 1990. It is the product of ultrasound scores, the menopausal score and the absolute value of serum CA125 levels)

U - Ultrasound score (it was expressed as 1 or 3 depending on ultrasonic features Table 1. Expressed as 1 if score is 0 or 1, and 3 if score is 2 or more)

M - Menopausal status (It was expressed as 1 if premenopausal and 3 if postmenopausal i.e. amenorrhoea more than 1 year or had hysterectomy and age >50 years)

CA-125 - The absolute values of serum CA-125 was entered directly into the mentioned equation.

The histopathological diagnosis was considered as the gold standard for defining the outcomes. Hence, the RMI was evaluated for sensitivity, specificity, positive (PPV) and negative (NPV) predictive values with reference to the actual presence of a malignant or benign pelvic tumor. Statistical analysis was done using Statistical Package for Social Sciences, SPSS version 16 of windows. A P-value <0.05 was considered to be significant. To determine the best cut-off value to discriminate between benign and malignant adnexal masses, a receiver operating characteristics (ROC) curve was plotted. The best cut-off value was chosen according to the highest sensitivity with the lowest false-positive rate.

Table 1. Scoring system based on USG findings

USG findings	Score
Multilocular cyst	1
Solid areas	1
Bilateral Lesions	1
Ascites	1
Intra-abdominal metastasis	1

RESULTS

The present study included 120 patients of which 91 (75.83%) patients belonged to rural area and 29 (24.17%) belonged to urban area (Fig. 1). As the study was conducted in a tertiary care government hospital so patients from rural area were in preponderance. Out of 120 patients, 78 (65%) patients showed benign disease and 42 (35%) had malignancy. The mean age of patients in benign group was significantly lower (36.84 years) as compared to malignant group (43.12 years) (Fig. 2). Of 78 patients with benign final pathologic results, 22(28.21%) had papillary serous cystadeoma, 15 (19.23%) patients had simple follicular cysts, 13 (16.67%) had dermoid cysts, 13 (16.67%) had endometriotic cysts, 2 (4.76%) had tubercular masses and 2(4.76%) patients had borderline malignant disease, while among the malignant group, 23 (54.76%) patients had papillary serous cystadenocarcinoma, 3 (7.14%) had dysgerminoma and Immature teratoma and 2 (4.76%) patients had metastatic disease and sex cord stromal tumors (Table 2). The distribution of benign and malignant cases according to menopausal status, USG score, serum CA-125 and various RMI score is shown in Table 3. The results revealed that 24 patients had menopausal score >3 and of these 14 belonged to the malignant group (32.56%) whereas 94 patients had menopausal score <3 and among these 65 (86.67%) had benign outcomes. This association was found statistically significant with a p value of < 0.0001. With regard to the USG score, 43 patients had USG score of 3 and among these maximum patients (62%) were found to be malignant. Similarly, 75 patients exhibited the USG Score 1 and among these 78% were with benign outcomes. This relationship was also found statistically significant.

Table 2. Distribution of patients on basis of histopathological diagnosis

Histopathological diagnosis	No. of patients (%)	
	RMI<200 (n=73)	RMI>200 (n=47)
Anaplastic dysgerminoma	0 (0.00)	1 (2.38)
Boderline mucinous cystadenoma	0 (0.00)	1 (2.38)
Boderline pappilary cystadenoma	0 (0.00)	1 (2.38)
Dysgerminoma	0 (0.00)	3 (7.14)
Dermoid cyst	13 (16.67)	0 (0.00)
Endometrioma	8 (16.67)	5 (10.60)
Endodermal sinus tumor	0 (0.00)	1 (2.38)
Fibrothecoma	0 (0.00)	1 (2.38)
Granulosa cell tumor	0 (0.00)	2 (4.76)
Immature teratoma	0 (0.00)	3 (7.14)
Malignant germ cell tumor	0 (0.00)	1 (2.38)
Malignant teratoma	0 (0.00)	1 (2.38)
Metastatic pappilary cystadenocarcinoma	0 (0.00)	2 (4.76)
Mucinous cystadenocarcinoma	5 (7.05)	0 (0.00)
Mucinous cystadenoma	7 (8.97)	0 (0.00)
Pappilary serous cystadenoma	22 (28.21)	0 (0.00)
papillary serous cystadenocarcinoma	0 (0.00)	23 (54.76)
Sertoli leydig cell tumor	0 (0.00)	1 (2.38)
Simple Follicular cysts	15 (19.231)	0 (0.00)
Tubercular mass	2 (2.56)	0 (0.00)
Theca cell tumor	0 (0.00)	1 (2.38)
Sclerosing stromal tumor	1 (1.28)	0 (0.00)

Table 3. Distribution of benign and malignant cases in relation to age, menopausal status, USG score, serum CA- 125 and RMI

Variables		Benign	Malignant	p-value
CA 125		66.28 ± 47.35	450.46 ± 452.08	<0.0001
Menopasual score	Score 1	65 (86.67)	29 (67.44)	<0.0001
	Score 3	10 (13.33)	14 (32.56)	
USG score	Score 1	59 (78.67)	16 (37.21)	<0.0001
	Score 3	16 (21.33)	27 (62.79)	
RMI		109.31 ± 205.40	1303.51 ± 1439.89	<0.0001

Table 4. Sensitivity, specificity, PPV, NPV of USG score, Menopausal score and CA 125

Variables	USG score (%)		Menopausal score (%)		CA 125 (%)
	Score-1	Score-3	Score-1	Score-3	
Sensitivity	86.67	88.46	78.57	85.71	64.62
Specificity	90.00	77.78	89.55	81.82	88.18
Positive predictive value	68.62	85.19	75.86	85.71	97.67
Negative predictive value	96.43	82.35	90.91	81.82	70.13
Accuracy	85.33	84.09	86.31	84.00	80.00

Table 5. Sensitivity, specificity, PPV, NPV of RMI scores at five levels viz., >50, 50-100, 100-150, 150-200 and >200

RMI	Per cent (95% CI)				
	<50	50-100	100-150	150-200	>200
Sensitivity	50.00 (6.76-93.24)	66.67 (9.43-99.16)	87.50 (7.35-99.68)	83.33 (35.88-99.58)	91.89 (79.09-98.30)
Specificity	93.33 (77.93-99.18)	93.75 (79.19-99.23)	90.00 (55.50-99.75)	87.50 (47.35-99.68)	83.33 (35.88-99.58)
Positive predictive value	67.92 (53.68-80.08)	50.00 (6.76-93.24)	87.50 (47.35-99.68)	83.33 (35.88-99.58)	97.14 (85.08-99.93)
Negative predictive value	88.06 (77.82-94.70)	96.77 (83.30-99.92)	90.00 (55.50-99.75)	87.50 (47.35-99.68)	62.50 (24.49-91.48)
Accuracy	-	-	-	-	90.69

Data presented in Table 4 showed that menopausal score of 1 exhibited the sensitivity of 78.57%, specificity 89.55%, PPV 75.86% and NPV 90.91% while the menopausal score of 3 showed sensitivity of 85.71%, specificity 81.82%, PPV 85.71% and NPV 81.82%. Accuracy determined for both was around 84%. Similarly, USG score 1 had sensitivity of 86.67%, Specificity 88.46%, PPV 68.62%, and NPV of 96.43% whereas, USG score 3 had sensitivity of 88.46%, Specificity of 77.78%, PPV 85.19% and NPV 82.35%, respectively (Table 4). Both had an accuracy of 84.09% in detecting malignancy. This showed that USG score could be used as a predictor in differentiating benign and adnexal masses. The mean value for CA 125 in the subjects with benign disease was 66.28 and the corresponding value in the subjects with malignant disease was 450.46 which were much higher than the benign group. This association between benign and malignant patients was found statistically significant.

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. RMI had better sensitivity compared to CA 125 levels. The Mean RMI Score in the malignant group was 1303.51 as compared to 109.31 in the benign group. This association between RMI score and presence of malignancy was found to be highly significant with a p value of <0.0001 (Table 3). The sensitivity and specificity of RMI scores was studied at five levels viz., >50, 50-100, 100-150, 150-200 and >200. The sensitivity, specificity, positive and negative predictive values of RMI score at each of these levels was calculated and is presented in Table 5. It is clear from the Table that RMI > 200 exhibited the best sensitivity of 91.89%, specificity 83.33% with PPV 97.14% and NPV 62.50%. The fall in the specificity observed in RMI>200 group as compared to 150-200 group is because of the fact that specificity is dependent on number of False positive cases which was lowest in this group. The accuracy achieved with RMI > 200 was 90.69% (Table 5). A Receiver Operating Curve (ROC) (Fig. 3 and 4) was plotted to observe the performance of RMI in predicting malignancy. Area under the curve for RMI>200 was 0.880, while for RMI 150-200 it was 0.926.

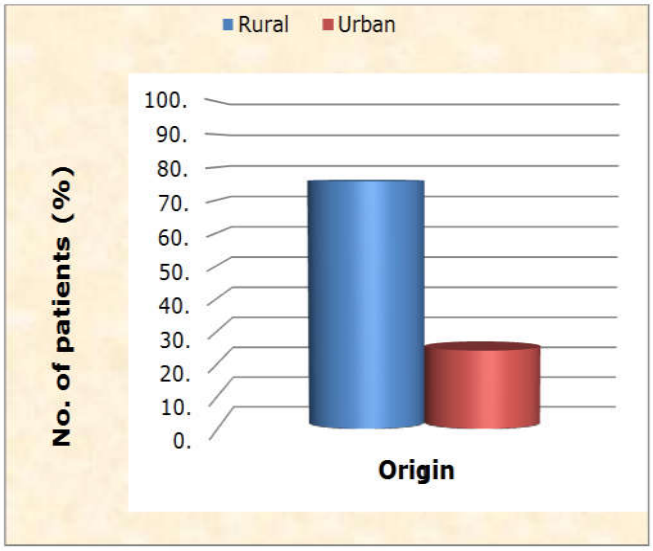

Fig. 1. Distribution of cases according to Residence

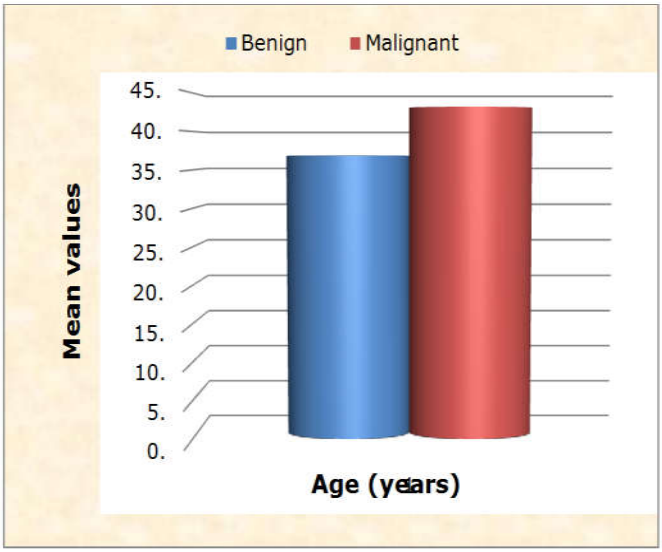

Fig. 2. Distribution of cases according to age

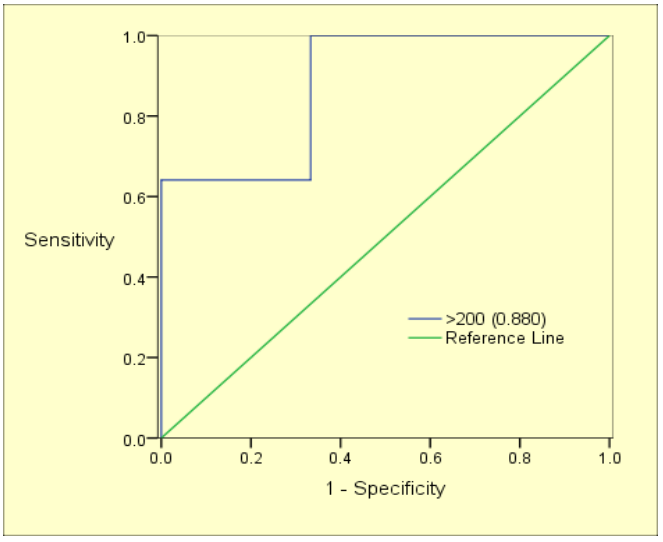

Fig. 3. Receiver operator characteristic curve showing relation between sensitivity and specificity in RMI >200

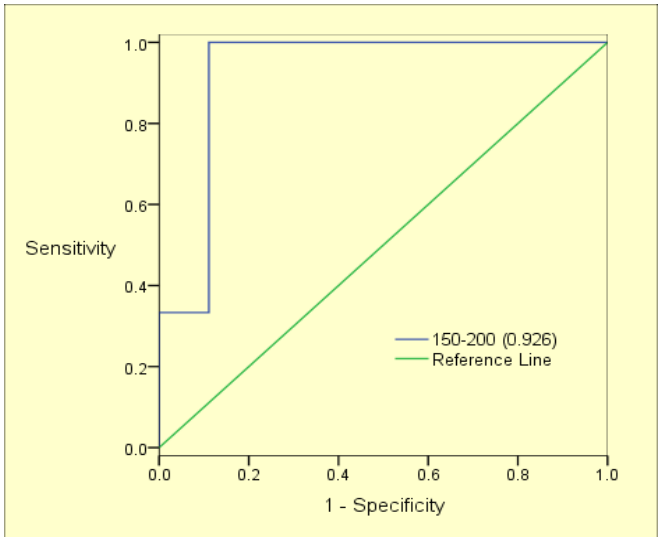

Fig. 4. Receiver operator characteristic curve showing relation between sensitivity and specificity in RMI 150-200

DISCUSSION

Ovarian cancer is responsible for the most deaths in the gynaecological sphere. It is the second most common gynaecological malignancy in developed countries, and is the leading cause of cancer deaths among women. It causes more mortality than all other gynaecological malignancies together. The main reason for this high mortality rate is the fact that the majority of women with ovarian cancer have advanced stage disease at the time of diagnosing. Five year survival in stage 1 disease is about 80%, whereas five year survival in stage II disease is 50%, which declines to 20% or less in stage III-IV disease. It is due to silent occurrence, slow progression and no effective methods for early diagnosis. Malignant tumours should be referred to specialized centres for gynaecological oncologic surgeries. Therefore differential diagnosis as benign and malignant tumours is essential in order to decide on the optimal approach in each case. To reduce the diagnostic dilemma between benign and malignant ovarian masses, a formula based scoring system known as risk of malignancy index (RMI) was introduced. The probability of malignant pelvic masses is calculated by incorporating serum CA-125

level, USG morphology of the pelvic masses and menopausal status. In the present study, the mean age of patients in the malignant group was significantly higher as compared to the benign group. This suggested that the chances of malignancy increases with the advancement in the age and reaches peri menopausal period. These results are in agreement with the earlier reports of Ashrafgangooei and Rezaeezadeh (2011). Kestane *et al*., (2014) in their study reported the slightly higher mean age in the benign as well as in the malignant group which might be due to the fact that higher percentage of postmenopausal patients were included in their study, whereas Akdeniz *et al*., (2009) reported much lower mean age of the patients as compared to the present findings which may be because of the smaller sample size. On demographic analysis, 75% of the patients belonged to rural area and 24% belonged to urban population. As the study was conducted in a tertiary care government hospital so patients from rural area were in preponderance. With regard to the histopathology of various tumors, 65% patients showed benign disease and 35% patients were found malignant. Among benign disease maximum patients (28.21%) had papillary serous cystadeoma which was followed by simple follicular cysts (19.23%), dermoid cysts and endometriotic cysts (16.67% each) while 4.76% patients showed borderline malignant disease. However, among the malignant group maximum (54.76%) patients had papillary serous cystadenocarcinoma, which was followed by dysgerminoma and Immature teratoma (7.14% each) and metastatic disease and sex cord stromal tumors (4.76% each). Mucinous Cystadenocarcinoma showed RMI<200 in all the 5 cases. This may be due to lower elevation of CA 125 levels in mucinous cancers. 10% of endometriomas showed False RMI>200. This was most likely due to falsely high levels of CA 125 found in endometriosis.

Ultrasonography is widely appreciated as the best imaging method for evaluation of ovarian pathology. In our study, 43 patients had USG score 3 and of these maximum patients were found to be malignant. Similarly, 75 patients showed USG Score 1 and of these 78% were with benign outcomes. Similar results were also observed by Campose *et al*. (2016). In the present study, the sensitivity and specificity for USG score in predicting malignancy was 88.46 and 77.78%, respectively. Study by Aziz and Najmi (2015) revealed that ultrasound was the best predictor of malignancy with a sensitivity, specificity and positive likelihood ratio of 78.3%, 81.5%, and 4.2, respectively. Similarly, study by Kestane *et al*., (2014) revealed sensitivity of almost 100% and specificity of 65%. In general all these studies showed that the recent development of ultrasound techniques and the better characterization of malignant masses by this method have led to better performance by ultrasound as a predictor of malignancy. In the present study, significantly maximum patients (94) showed menopausal score <3 while 24 patients had menopausal score >3 and among these 14 belonged to the malignant group and 65 had benign outcomes. These results were in accordance with the study of Kestane *et al*. (2014) who reported that higher menopausal scores were found in patients with malignant diseases. Also the study conducted by Jacobs *et al*. (1990) shows that menopausal score if used as individual criteria proved to be statistically significant. Ashrafgangooei and Rezaeezadeh (2011) observed more number of malignant cases with a higher menopausal score. Similar results were also reported by Campose *et al*., (2016). The present study revealed a sensitivity of 85.71% and specificity of 81% for menopausal score 3 to detect malignancy which is in line with the previous reports of Aziz and Najmi (2015). However, Jyothi (2014) reported slightly lower values of sensitivity and specificity as compared to the present findings which may be due to the small sample size with less number of patients being postmenopausal.

Several candidate biomarkers and their combinations have been employed in assessing the risk of ovarian malignancies with varying efficiency. Serum CA125 level is widely appreciated as a useful biomarker for estimating the risk of ovarian cancer, though other gynecological pathology like endometriosis can also increase its levels. In the present study, mean CA 125 levels in patients with malignant disease was significantly higher as compared to the benign pathology. These results are in close agreement with the earlier reports of Ashrafgangooei and Rezaeezadeh (2011), Kestane *et al*. (2014), Chopra *et al*. (2015) and Campose *et al*. (2016). Torres *et al*. (2002) conducted a study on 158 patients and reported that the best individual performance was found in CA 125 levels (sensitivity of 78%, specificity of 75%). Similarly our study reported a sensitivity of 64.62% and specificity of 88.18% with an accuracy of 80% for CA 125 in predicting malignancy. A study by Jyothi (2014)[12] reported a sensitivity and specificity of 80% and 93% for CA 125 which is in accordance with the present findings, respectively. Similarly, Asif *et al*. (2004) reported a sensitivity and specificity of 83% and 82% respectively which is closer to the present study. In general, all these studies including the present one indicates that CA 125 marker to be an important predictor of malignancy.

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. RMI had better sensitivity compared to CA 125 levels. The mean RMI score in the malignant group was significantly higher than the benign group. These results are comparable to the previous study of Ashrafgangooei and Rezaeezadeh (2011) who reported mean RMI score as 21.7 and 1062 in the benign and malignant patients, respectively. In order to identify the RMI score that was an effective risk predictor, the sensitivity and specificity of RMI scores were studied at five levels and it was found that RMI> 200 was superior in terms of sensitivity, specificity, PPV and NPV as compared to RMI 150-200 group. Majority of the false negative cases were of mucinous type ovarian cancers which showed lower RMI values. This may be possibly because of lower levels of CA 125 found in patients with mucinous malignancies. Similar results were also reported by Torres *et al*. (2002) and Obeidat *et al*. (2004). The present findings were also consistent with study done by Jyothi (2014) who reported sensitivity of 88.5% (RMI >200) for diagnosing invasive disease. The overall sensitivity of this algorithm for diagnosing all borderline, invasive ovarian or primary peritoneal disease was 87.4%, and the specificity was 86.8%.

In the present study ROC Curve analysis was plotted to observe the performance of RMI in predicting Malignancy. Area under the Curve (AUC) for RMI>200 was slightly lower than the AUC achieved by 150-200 RMI group. This was due to less number of false negatives and false positive results in this group. Asif *et al*. (2004) conducted a study to the effectiveness of RMI in preoperative diagnosis of ovarian masses. Receiver operating characteristic (ROC) curves revealed that RMI was a better discriminant than CA 125 alone

for differentiating between benign lesions and malignant ovarian tumours with AUC of 0.86. Another study conducted by Ashrafgangooei and Rezaeezadeh (2011) proved that RMI at a cut off 200 had best area under the curve on ROC analysis than any other parameter used alone. So it confirms the applicability of RMI>200 in diagnosing adnexal masses with high risk of malignancy. It can be easily introduced into clinical practice to facilitate the selection of the patients for surgery and also helpful in triaging patients to different treatment groups.

Conclusion

The present study concluded that RMI was a better estimate in diagnosing adnexal masses with high risk of malignancy and subsequently guiding the patients to gynecological oncology centers for suitable and effective surgical interventions compared with individual parameters of ultrasound score, CA-125 or menopausal score. Simplicity and applicability of the method in the primary evaluation of patients with pelvic masses makes it a good option in daily clinical practice in non-specialized gynecological departments.

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