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A PROSPECTIVE STUDY ON DIAGNOSTIC ACCURACY OF RISK OF MALIGNANCY INDEX IN PREOPERATIVE ASSESSMENT OF OVARIAN TUMOURS IN TERTIARY CARE CENTRE OF SOUTH INDIA.

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ABSTRACT

Background: Among Gynaecological malignancies in India, leading cause of mortality is Ovarian cancer, varying between 5.4 – 8 per 1,00,000 population. Using a combination of Diagnostic modalities such as pelvic examination, CA 125 marker levels , Ultrasonography to predict whether an adnexal mass is benign or malignant a mathematical formula was developed as RISK OF MALIGNANCY INDEX (RMI). **Methods:** This study was a Prospective study conducted in the Department of Obstetrics and Gynaecology in Government Thanjavur Medical College, Thanjavur over a period of one year from 2019-2020 in a study population consists of 100 patients who were admitted with adnexal mass. RMI score= Menopausal score(M) × Ultrasound Score(U)× CA 125(u/ml). The Histopathological findings of excised tumors were analysed after surgery in order to determine the final diagnosis. **Results:** Our study reported the prevalence of malignancy as 18% in a study population of 100.Our study shows the diagnostic performance of RMI at 200, sensitivity 56.5 %, specificity 93.1%, positive predictive value 72.2 %, negative predictive value 87.8% respectively. **Conclusion:** RMI discriminates Ovarian masses into benign and malignant with high specificity and also decided for early referral to Gynaecological ontological centre when it is in operable state.

KEYWORDS : RMI, USG, HPE, CA 125, Positive predictive value(PPV), Negative predictive value(NPV).

INTRODUCTION

Ovarian cancer is the 3rd most common cancer in India, contributes to 5.6% per population. Ovarian cancer is 1% to 1.5 % of risk being diagnosed in a life time and almost 0.5 % mortality was reported.[1,2] The milestone to reduce the mortality is an early detection and timely referral to Gynaecological oncologists. Preoperative diagnostic procedures, which is able to distinguish between benign and malignant neoplasms, could be useful in planning optimized treatment because there is a challenge in accurate diagnosis for general gynaecologists because of its atypical and bizarre behaviour. Repeat evaluation of RMI that can be easily used by general gynaecologists and matching the results with histopathology, the gold standard. RMI at the cut off value of 200 was proved to be best .[1,2]

Optimal initial cytoreductive surgery performed by Gynaecological oncologists, depending upon stage and histological type increases the disease free interval and survival rate.Of all ovarian cancers, 65-85% prevalence has been reported globally, mostly focussing the risk factors on epithelial ovarian cancer but primary malignancies importance cannot be over emphasized as a step towards their etiology and behaviour understanding.[1] RMI is a simple and cost effective method which can be used by general gynaecologists at less specialized centre to differentiate between malignant from benign and borderline masses.

RMI score was developed by Jacobs et al in 1990 using a combined mathematical formula defined as a product of menopausal score, ultrasound score and absolute level of CA 125 and termed as RMI 1.[1] RMI was developed further by Tingulstad et al in 1996(RMI 2) and 1999 (RMI 3).[2,3] The difference between these 3 indices lies in different scoring for ultrasound findings and menopausal status. In 1999 Morgante et al., tested indices with evident malignant criteria in ultrasonography such as distant or hepatic metastases and reported that RMI 2 performed better for detecting ovarian malignancy.[4] Subsequently RMI 4 was developed by adding tumor size as a parameter by Yamamoto et al (2009) and RMI 5 was developed by using Doppler blood flow as an additional parameter.[5] Many papers published in this issue on different populations and yielded different results. RMI value in a general population was investigated by majority of prior studies and only few studies explored RMI in premenopausal and postmenopausal women [Terzic et al (2013), Sayanesh et al (2013), Kaijser et al (2013), Vasudevan et al (2017).[6]

MATERIALS AND METHODS

This prospective study was performed in the Department of Obstetrics and Gynaecology, Thanjavur Medical College and Hospital. The study was conducted during the period of 2019-2020. The study population consisted of 100 patients who were admitted in our hospital with adnexal masses.

Inclusion Criteria

Patients above the age of 30 years admitted in our hospital in premenopausal and postmenopausal age group with the diagnosis of an ovarian mass were included in this study.

Exclusion Criteria

Ovarian mass in pregnant women were excluded because of elevated CA 125 which gives false positive results. Simple cyst <2cm in premenopausal women and extra ovarian mass and inoperable ovarian mass are excluded from the study.

Serum CA 125 and the Ultrasound examination were performed at the time of preoperative laboratory assessment which was usually accompanied approximately within 1 week prior to surgery. Serum CA 125 was determined by Radioimmunoassay. Ultrasound score (U) was assigned for the following features. Unilateral/bilateral, Unilocular /multilocular, Solid areas, Ascites, Intra abdominal metastases. An ultrasound score of 1 was given for none or one of the features was found and score of 3 for two or more of the features were shown.

In Menopausal Score (M), Postmenopausal score was defined as >1 year of amenorrhoea or >50 years of age who had hysterectomy, they were assigned as M=3, and those who did not meet these criteria were defined in a Premenopausal score (M=1). The absolute values of CA 125 was entered in formula. Ultra sonographic examination of pelvic organs was performed, menopausal status and level of cancer antigen 125(CA 125) were assessed and finally RMI was calculated for all the patients. RMI was calculated using the formula RMI Score=Ultrasound Score(U) x Menopausal Score(M) x CA 125(U/ml)

The Histopathology is considered as Gold Standard for defining the outcomes finally. RMI is an index which indicates malignancy with reference to the actual presence or absence of malignancy in the ovarian mass.

Interpretation of RMI Score

If the score is 1) <25= low risk,2) 25-250= moderate risk,3)

>250=high risk. Validated results of RMI were compared with histopathologically confirmed lesions. In many studies, for predicting malignancy 200 is taken as a cut off value but according to RCOG guidelines, at higher cut off values detection of true negative cases will be increased.[7]

Statistical Analysis

Data were analysed using chi square tests. Descriptive statistics were used for demographic data and summarized as mean with standard deviation or frequency with percentage. Univariate analyses to determine the association of each parameter were performed using Student's t test. The independent association was then determined by logistic regression. The diagnostic performances were reported as Sensitivity, Specificity, Positive Predictive Value and the Negative Predictive Value with 95% confidence interval. Diagnostic accuracy was determined with reference to the actual presence of malignant or benign tumor.

OBSERVATION AND RESULTS

The study included 100 patients with ovarian mass of which 82 patients have benign mass and 18 patients have malignant ovarian mass. In this study Serous Cystadenoma is the most common tumor accounting for 24% of the total tumors and 29.26% of the benign tumor. Mucinous Cystadenoma is the second most common benign tumor accounting for 20% of total and 24.39% of benign tumor. Next most common is Dermoid which constitutes 11% of total and 13.41% of benign tumor. In this study the most common malignant tumor is Serous cyst adenocarcinoma constitutes 5% of total and 27.7% of malignant tumor. Next most common tumor is Granulosa Cell Tumor constitutes 4% of total and 22.22% malignant tumor.

Table 1. Histopathological Incidence of Benign and Malignant Ovarian Tumor (n=100).

Benign tumors (n=82)	Malignant Tumors (n=18)
Serous cystadenoma-29.26% (24)	Serous cystadenocarcinoma-27.7% (5)
Mucinous cystadenoma – 24.39% (20)	Granulosa Cell tumor-22.2% (4)
Dermoid-13.41% (11)	Mucinous Cyst adenocarcinoma- 11.11% (2)
Simple Serous Cyst -10.97% (9)	Krukenberg Tumor-11.11% (2)
Simple Mucinous Cyst - 2.43% (2)	Endometrioid Adeno Carcinoma -11.11% (2)
Corpus Luteal Cyst- 4.87% (4)	Germ Cell Tumor- 5.55% (1)
Follicular Cyst-9.75% (8)	Borderline Mucinous Tumor-5.55% (1)
Endometriotic Cyst -4.87% (4)	Clear Cell Carcinoma -5.55% (1)

In the age group of 31-40 years of age 54.87% of cases are Benign, whereas in 41-50 years of age only 33.3% are Malignant. The 54.87% Benign ovarian tumors are more common in 31-40 years of age and 33.3% Malignant ovarian tumors are more common in age group of 41-50 years. In this study, among the 18 patients of postmenopausal women, 44.4% have malignant tumors.10.7 % have regular cycles and 15.38% have irregular cycles have malignant ovarian tumors. In this study, among the patients with malignant tumor, n=18. The 44.44% of malignant ovarian tumor belong to postmenopausal age group whereas 12.2% of the women with benign tumor are in postmenopausal age group.

Table 2. Distribution of Cases According to Age, Parity, Menstrual Cycles.

Parameters (n=100)	Benign	Malignant
Age		
31-40	(45)54.87%	(3)16.7%
41-50	(24)29.26%	(6)33.3%
51-60	(7)8.5%	(4)22.2%
>60	(6)7.31%	(5)27.7%
Parity	22(78.5%)	6(21.4%)
Nulliparous	60(83.3%)	12(16.6%)
Multiparous		
Menstrual cycles		
Premenopausal		
Regular	(50)89.3%	(6)10.7%
Irregular	(22)84.6%	(4)15.4%
Postmenopausal	(10)55.5%	(8)44.4%

Among 82 patients in premenopausal age group 69.44% of patients with benign tumor have regular cycles where as the remaining have irregular cycles .60% of patients with malignant ovarian tumor have regular cycles and 40% have irregular cycles. In our study, 28 patients are Nulliparous and 72 patients are Multiparous women. In 28 nulliparous women 78.5% have benign tumors, whereas 21.4% have malignant ovarian tumors. Among multiparous women 83.3% have benign and 16.6% have malignant ovarian tumors. Among the 82 patients with benign tumors ,26.82% are nulliparous and 33.3% are multiparous and among 18 patients with malignant tumors 33.3 % are nulliparous and 66.6% are multiparous. Sensitivity of Parity index is 16.6% and Specificity is 78.5%. Positive predictive value is 66.6% AND Negative predictive value is 26.8%.

Table 3.. Menopausal Status

	Benign	Malignant
Premenopausal	72(87.8%)	10(12.2%)
Postmenopausal	10(55.5%)	8(44.4%)

In our study 82 patients are in premenopausal age group and 18 patients are in postmenopausal age group. Among 82 premenopausal patients have benign tumors accounting for 87.8% and have malignant tumors accounting for 12.2%. Among 18 patients postmenopausal women have benign tumors accounting for 55.5% and patients have malignant tumors accounting for 44.4 %.

Table 4. Comparison of Premenopausal and Post-menopausal Score.

	Premenopausal	Postmenopausal
Benign	72(87.8%)	10(12.2%)
Malignant	10(55.5%)	8(44.4%)

Among 82% benign tumors, 87.8% of patients are in premenopausal age group and 12.2% in postmenopausal age group. Among 18 patients with malignant tumors 55.5% are in pre menopausal age group and 44.4% are in postmenopausal age group. Sensitivity Specificity, Positive predictive value and Negative predictive value of menopausal score are 44.4%,87.8% ,44.4 % and 87.8% respectively.

Table 5 .Ultrasound Score

Ultrasound score	Benign	Malignant
USG score=1	43(95.5%)	2(4.4%)
USG score =3	39(70.9%)	16(29.1%)

In this study, 45 patients have ultrasound score of 1 that is presence of one or more of the parameters in ultrasound. Among 45 patients, 95.5% have benign tumors and 4.4% have malignant tumors. 55 patients have ultrasound score of 3 indicating presence of 2 or more parameters of ultrasound criteria. Among 55 patients with ultrasound score of 3, 70.9% have benign tumors and 29.1% have malignant ovarian tumors.

Table 6.Comparison Between Ultrasound Score 1 and Score 3

	USG score =1	USG score =3
Benign	43(52.4%)	39(47.5%)
Malignant	2(11.1%)	16(88.8%)

On analysis, among 82 benign tumors 52.4% have ultrasound score of 1 and 47.5% have ultrasound score of 3. Among 18 malignant ovarian tumor 11.1% have ultrasound score of 1 and 88.8% have ultrasound score of 3. The performance status of ultrasound score has been analysed with sensitivity of 29.9%, specificity of 95.5%, positive predictive value of 88.6% and negative predictive value of 52.4% respectively.

Table 7. CA 125 Cut off 35

CA 125	Benign	Malignant
<35	41(91.1%)	3(6.7%)
>35	41(73.2%)	15(26.8%)

CA 125 is analysed with cut off value of 35 u/ml. Normal range is 035u/ml. In our study, CA 125 with cut off value of 35u/ml 56 patients have >35u/ml. Among them 73.2% have benign lesions and 26.78% have malignant lesions .91.1% of patients with CA 125<35u/ml have benign lesions and 6.6% have malignant lesions.

Table 8.Comparison of CA 125 (<35 or >35) and HPE.

HPE	<35	>35
Benign	41(50%)	41(50%)
Malignant	3(16.6%)	15(83.3%)

Among 82 patients with benign tumor, 50% have CA125<35 and 50% have CA 125 >35u/ml, whereas the patients with malignant ovarian tumor 16.6% have CA 125 <35U/ML and 83.3% have CA125>35 u/ml. Sensitivity of 26.8% Specificity of 93.1% Positive Predictive Value of 83.3% and Negative Predictive Value of 50%.

Table 9. Management Strategies of Ovarian Tumours.

Type of Ovarian tumours	Laparoscopy	Laparotomy
Benign	16(19.5%)	66(80.4%)
Malignant	1(5.5%)	17(94.4%)

In ovarian lesions, the management strategies depends upon the symptoms attributable to adnexal lesion, suspected malignancy in adnexal lesion and patient's choice in treatment. In our study, out of 82 cases in benign lesions, only 19.5% cases undergone laparoscopic procedures and 80.4% undergone staging laparotomy. Out of 18 cases in malignant adnexal lesions, 94.4% cases undergone staging laparotomy and 5.5% undergone laparoscopic procedure. In Laparoscopic procedures, out of 19.5% cases in benign lesions, 9.75% of cases were follicular cyst and 9.75% cases were dermoid cyst. In malignant lesions, borderline mucinous tumor undergone Laparoscopic intervention.

Table 10 .RMI Score Cut off at 100,150, 200,250.

RMI cut off (n=100)	Benign tumors	Malignant tumors
100		
<100	56(98.2%)	1(1.7%)
>100	26(60.4%)	17(39.5%)
150		
<150	66(95.6%)	3(4.34%)
>150	16(51.6%)	15(48.4%)
200		
<200	72(93.5%)	5(6.32%)
>200	10(43.4%)	13(56.5%)
250		
<250	76(92.6%)	6(7.31%)
>250	6(33.3%)	12(66.6%)

Table 11. Diagnostic Accuracy of RMI 100,150, 200, 250 in Terms of Sensitivity, Specificity, PPV, NPV

RMI cut-off	Sensitivity	Specificity	PPV	NPV
RMI 100	39.4%	98.24%	94.4%	68.2%
RMI 150	48.3%	95.6%	83.3%	80.4%
RMI 200	56.5%	93.5%	72.2%	87.8%
RMI 250	66.67%	92.68%	66.67%	92.68%

The risk of malignancy index based on USG Score, CA 125 and Menopausal Score was calculated preoperatively. With the cut off value of 100, 57 patients are below 100 and 43 patients are above 100. 98.2% of patient with RMI <100 have benign tumors and 1.75% patients have malignant tumors. In 43 patients in RMI>100, 60.46% have Benign lesions and 39.53% have malignant lesions. The sensitivity of RMI with cut off value of 100 is 39.53%, specificity 98.24%, positive predictive value is 94.4%, negative predictive value is 68.2% respectively.

Among 69 patients with RMI cut off value of <150, 95.6% patients have benign tumors and 4.34% have malignant tumors. 51.6% of patients with RMI Cut Off >150 having benign lesions and 48.4% of patients are having malignant lesions. The diagnostic performance of RMI cut off value 150 is having sensitivity 48.3%, specificity 95.6%, positive predictive value 83.3%, negative predictive value 80.4% respectively.

Among patients with RMI cut off value 200, 78 patients have RMI <200 and 22 patients have RMI>200. With RMI cut off value <200, 93.5% have benign lesions and 6.3% have malignant lesions. RMI cut off value 0f >200 43.4% have benign tumors and 56.5% have malignant tumors. Sensitivity of 56.5% , Specificity of 93.5% ,Positive predictive value of 72.2% and Negative predictive value of 87.8%.

Among 84 patients with RMI cut off <250, 92.6 % have benign lesions and 7.31% malignant lesions. For RMI cut off >250 33.3% have benign lesions and 66.6% have malignant lesions. The Diagnostic Performance of RMI cut off value 250 is having sensitivity 66.67% specificity 92.68%, positive predictive value 66.67%, negative predictive value 92.68% respectively.

The sensitivity of RMI is high with the cut off value of 250 in discriminating benign and malignant ovarian tumors. The sensitivity increases as the cut off value increases. The specificity of RMI is high with cut off value 100 .The specificity decreases as the cut off value increases. Likewise the PPV is high with cut off value of 100 and it decreases as the cut off value increases. NPV is high with the cut off value of 250 and increases as the cut off value of RMI increases. The optimal sensitivity, specificity, PPV and NPV for RMI is high at the cut off value of 200. The cut off value of RMI at 200 is statistically significant, associated with gold standard (HPE) i.e., benign or malignant.

Table 12. Comparison of Various Parameters- Parity, Menopausal Score, Ultrasound Score, CA 125.

	Sensitivity	Specificity	PPV	NPV
Parity	16.6%	78.5%	66.6%	26.8%
Menopausal score	44.4%	87.8%	44.4%	87.8%
Ultrasound score	29.9%	95.5%	88.8%	52.4%
CA 125	26.8%	93.1%	83.3%	50%
RMI 200	56.52%	93.51%	72.22%	87.8%
RMI 250	66.67%	92.68%	66.67%	92.68%

The sensitivity of PARITY as a diagnostic indicator is low as 16.6%, whereas the specificity is high as 78.5% and PPV 66.6 % and NPV 26.8 %. The Menopausal Score have sensitivity 44.4%, specificity 87.8% and PPV is 44.4% and NPV is 87.7%.It has high specificity and NPV. The Ultrasound Score has sensitivity 29.9%, specificity 95.5% ,PPV 88.8% and NPV 52.4% in its diagnostic modality. It has HIGH Specificity and NPV. For CA 125 with the cut off value of 35U/ML has sensitivity 26.8%, specificity 93.1%,PPV 83.3%,NPV 50% in its diagnostic performance .It has high Specificity and PPV.

The Diagnostic Performance of sensitivity, specificity, PPV and NPV of RMI at the cut off value of 200 are 56.5%, 93.51%, 72.22% and 87.8% respectively and in our study the diagnostic performance of RMI at the cut off point 250 had high sensitivity(66.67%) and high specificity(92.68%) and positive

predictive value of 66.67% and negative predictive value of 92.68% respectively. We found the RMI has Better Diagnostic Performance than CA125, menopausal score and USG score.

DISCUSSION

Our study, address the validity of RMI index in correlating presumptive diagnosis of ovarian mass in perimenopausal and postmenopausal women. RMI score will helps in preoperative diagnosis and early intervention based on the fact that survival rate of stage 1a in ovarian carcinoma is 80%. In our study, Mean age of the patient was 44.72 years and shows the incidence of (33.3%) Malignant ovarian tumors in 41-50 years of age and (54.87%) benign tumors in <40 years of age. Before 40 years of age, ovarian carcinoma is very rare and thereafter it rises steadily .In our study, maximum number of cases were in the 3rd and 4th decades and percentage of malignant ovarian masses were low in this age group. Risk of malignancy is increased by early menarche and late menopause. There was no significant association between the age of menarche and risk of malignancy in our study. However, in early menarche age group 28% of malignancies were seen.

Risk of ovarian malignancy is 3 fold decline in Pregnancy and 2 fold rise in risk by Infertility . Because of the fact that anovulation and secretion of pituitary gonadotropins are suppressed by Pregnancy. In our study, incidence of malignant tumor among Nulliparous women was 33.3% and Multiparous women was 66.6%. Parity score had low sensitivity(16.6%), high specificity (78.5%) and positive predictive value was 66.6% and negative predictive value was 26.8% with diagnostic accuracy of 34.00%. However ,the low diagnostic performance of parity is not statistically significant in our study. According to the menopausal status, 87.8% majority of cases were in premenopausal age group. The percentage of malignant ovarian tumors was more in premenopausal age (55.5%) compared to postmenopausal age (44.4%). Probably, this difference lay on the characteristics and associated findings of the tumors in each case studied. In our study the menopausal score was the weakest constituent of RMI, having 44.4% sensitivity and 87.8% specificity, results were comparable with study of Jenitha et al.[8] However, various other studies reported that ovarian cancer is more common in postmenopausal age group.

Our present study is mainly focussed on RMI which is an integrated mathematical score of Menopause, CA 125 and USG score. Therefore, Menopausal status alone cannot be used as an indicator of malignancy. For postmenopausal score of 3, higher sensitivity, specificity, positive predictive value and negative predictive value has been reported by Rao et al (2014).[9] In assessing the malignancy risk, high specificity and low sensitivity has been reported by our study for menopausal score. For the accurate referral of invasive malignant masses to gynaecological oncologists we have developed RMI score. In a study conducted by Yamamoto et al ., borderline malignancies are allocated to malignant group, whereas in our study we chose to allocate it in benign group. However this allocation does not explain the results, which was varying between the studies. Most cases of borderline malignancies behave in a benign manner, but some have invasive implants which require gynaecological debulking significantly, because most of them are stage 1 tumors (90%).[10]

The accuracy of RMI performs better when we allocate borderline malignancies as malignant, but it is not statistically significant. To define the preoperative characteristics of ovarian tumor, the only parameter which is in use in daily clinical practice was Ultrasound. As there is no evidence in literature, for the highly expected correlation, between the features as defined by ultrasound and pathology report. But recently, several tumor variables were assessed for their correlation with the malignancy. For the evaluation of ovarian pathology, the widely appreciated best imaging modality is Ultrasonography, reported higher sensitivity, specificity, positive predictive value and negative predictive value in several studies. Among the parameters evaluated, our study reported for an ultrasound score of 3, had sensitivity 29.9%, specificity 95.5%, positive predictive value 88.6% and negative predictive value of 52.4%. In the present study, USG score had higher specificity and positive predictive value has been reported.

Although with varying efficiency, the risk of malignancies were assessed by using several biomarkers and their combinations. The widely appreciated useful biomarker for risk of malignancy estimation is SERUM CA 125 level, though its levels have also been increased by other pathological conditions in gynaecology. Earlier studies such as Mayers et al and Simsket et al reported less than 80% sensitivity and specificity. [11,12] Our study reported sensitivity of 26.8%, specificity of 93.1%, positive predictive value of 83.3% and negative predictive value of 50% for CA 125 >35u/ml respectively. This findings of CA125>35u/ml in our study, correlates with the results published in J Med Assoc Thai in which 23% and 89% of benign and malignant tumors were reported respectively.[13] To infer that ovarian mass is malignant, it is not necessary for CA 125 level should be more than 35u/ml but if it is less than 35u/ml it denotes that tumor is not malignant. Majority of our patients had elevated levels of CA 125, which was mainly contributed by higher prevalence of inflammatory, non specific ovarian and uterine pathology, like pelvic inflammatory diseases and endometriosis.[14]

CA 125 had low diagnostic performance in detection of malignant ovarian disease, is attributable to its variable levels in premenopausal women with adnexal masses, regarding phases of menstrual cycles and its more specificity for non mucinous tumors.[15] But at the same time CA 125 is a good predictor and prognostic marker of ovarian cancer. To predict malignancy in ovarian neoplasms, by transforming ovarian morphological description into numerical objective data, a multi parametric tool, RMI is used. Several studies reported retrospectively and prospectively, that RMI is the best available tool for triaging and for referral of ovarian malignancies, which overcomes the high false positive rates of individual contributors of RMI i.e., Menopausal score, Ultrasound score and CA 125 levels.[6] As a diagnostic tool, its utility is depends on the prevalence of malignancy in the study population. Our study reported the prevalence of malignancy as 18% in a study population of 100.

With a cut off value of 200, JACOBS et al (1990) reported sensitivity of 85.4% and specificity of 96.9% in 143 cases of study population.[1] In estimating the risk of ovarian malignancy, the sensitivity and specificity of RMI score is superior when compared to other parameters, have been reported by several groups subsequently. Geomini et al (2009)reviewed many studies where the RMI cut offs were ranged from 25 to 250.[16] The diagnostic accuracy and performance of RMI is increased with the cut off value of 200, had been reported by many studies. Using a cut off value of 450, Yamamoto et al (2009) reported a sensitivity and specificity of 75% and 91% respectively.[5] At the cut off value of RMI>200, the reported sensitivity of 88.5% by Bailey et al and at the cut off value of 250, the reported sensitivity by Enakpene et al was 88.2% and specificity of 74.3% respectively.[17,18] In our study, at the cut off value of RMI>200 reported sensitivity of 56.5%, specificity of 93.5%, positive predictive value of 72.2% and negative predictive value of 87.8% respectively. Many studies reported the best cut off point for RMI was 200.

In 2009, Geomini et al reviewed, 116 diagnostic studies for adnexal malignancy, reported sensitivity of 78% and specificity of 87% for malignant masses at the cut off value of

RMI 200, which was near equivalent to our results.[16] At the cut off value of RMI 250, our study reported best diagnostic performance, yielded high sensitivity (66.67%) and high specificity (92.68%) PPV (66.6%) and NPV (92.6%) respectively, comparable to the majority of earlier reports which employed with the similar cut off. As per our study reports, RMI was suggested to be better than other single parameters, this because of our results for RMI were in agreement with the other studies. Decision at the cut off value (action line) should balance the sensitivity and specificity on one side and the local resources and specialists availability on other side. This is due to the fact that, if cut off values were low, the sensitivity increases at the expense of specificity whereas, at the higher cut off values the specificity increases at the expense of sensitivity. And majority of benign cases will be referred as malignant.[19]

In cases where limitations occurs, with regard for their referral to specialists, due to distance resources, RMI can be increased at the expense of sensitivity to achieve at the higher level of specificity. In any scoring systems, for diagnosing ovarian cancer using screening tests in a low risk population, false positive rates are important and to exclude malignancies, the false negative rate should ideally be zero or close to zero. In our study, 82 cases are benign tumor and 18 cases are malignant tumor. At the cut off value of RMI 200, True Positive cases were 13, True Negative – 72, False Positive-5, False Negative -10. Out of 5 false positive cases, 2 cases were Mucinous cystadeno carcinoma, 1 case was Germ cell tumor, 1 case was Serous cystadeno carcinoma and 1 case was Krukenberg tumor. Out of 10 false negative cases, 7 cases were Serous cyst adenoma, 3 cases were Mucinous cyst adenoma.

In our study, the Mean RMI was 165.84% (95% confidence interval 119 to 213) with standard deviation 240.68, which was statistically significant. To explain the false negative results in our study, besides low ultrasound score (subjective), CA 125 had high specificity more for non mucinous epithelial tumors than mucinous tumors. In a study conducted by Gadduci et al, reported non mucinous tumors expressed more CA 125 than mucinous tumors.[20] Our study analysed the performance of RMI at various cut off levels of 100, 150, 200 and 250 using sensitivity, specificity, positive predictive value and negative predictive value. The best cut off value of RMI is 200 which have been shown by various studies. Our study shows the diagnostic performance of RMI at 200, sensitivity 56.52%, specificity of 93.51%, positive predictive value 72.2% and negative predictive value of 87.8% respectively. As opposed to this, the study by Jacobs et al(1990) reported sensitivity of 85.4% and specificity of 96.9%, whereas Morgante et al (1999) showed sensitivity 58% and specificity 95%.[1,4]

Yamamoto et al (2009) at the cut off value of RMI 450, had reported sensitivity and a specificity of 75% and 91% respectively[5]. Mulder et al (2020) reported that at the cut off point of RMI >200, diagnostic discrimination between benign and malignant ovarian masses was not enough.[19] The limitation of this study was due to insignificant distribution between age and menopausal status, inter-observer discrepancies in ultrasound parameters and also smaller number of postmenopausal women were included in this study and limitations in detecting borderline malignancies. The diagnostic performance of RMI in detecting borderline lesions had reduced sensitivity which was reported by Tingulstad et al.[3] To overcome this limitations, more studies are recommended to establish the relation.

SUMMARY

In a study population of 100 cases, 48 cases were in 31-40 years, 30 cases were in 41-50 years , 11 cases were in 51-60 years of age and 11 cases were in age group of more than 60 years, 82 cases were BENIGN and 18 were Malignant Ovarian tumors. Our study analysed the diagnostic performance of RMI at the cut off value 250, the sensitivity, specificity, positive predictive value and negative predictive value were 66.67%, 92.68%, 66.67% and 92.68% respectively. Our study reported that CA 125 was highly specific and high positive predictive value. In predicting the malignancy risk, RMI score has better performance than CA 125, Ultrasound score and Menopausal score.

CONCLUSION

RMI is the best screening method, this study confirms its diagnostic accuracy and also highlights its limitations in excluding benign and borderline masses. So as to decrease the false positive and false negative cases more studies are required to establish the relation between benign and borderline tumors.

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