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Original Research Article

Decoding the diagnostic landscape of adnexal masses: a retrospective observational study at a tertiary care centre assessing the efficacy of the RMI-2 index

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ABSTRACT

Background: This study aimed to determine the utility of RMI 2 in distinguishing benign and malignant adnexal masses in low-income countries.
Methods: For the purpose of this retrospective observational study, relevant data from patients who attended a tertiary care institution in central Gujarat between June 2020 and June 2022 were obtained from the Medical Records Department (MRD). Ultrasound and biochemical parameters along with epidemiological factors were identified and an RMI 2 score was calculated followed by statistical analysis.
Results: Twenty-five (37.87%) of the sixty-six instances that were investigated were benign, two (3.03%) were borderline, and thirty-nine (59.09%), were malignant. Using RMI 2 at the traditional cut-off value of 250, results showed a sensitivity of 85.2% (95 %; CI=68.9-95.05), a specificity of 66.6% (95 %; CI=47.1-82.7 %), a positive predictive value of 74.36%, and a negative predictive value of 80.0 %. The ROC showed an AUC of 0.68 (CI=0.5-0.7) with a standard error of 0.07 (p=0.009).
Conclusions: With a cut-off point of 250, RMI 2 was able to identify malignant masses with an 85.2% sensitivity and 66.6% specificity to enable timely referral to more advanced institutions for improved management in resource-constrained settings where its affordability and user-friendliness are favourable.

Keywords: Adnexal mass, Risk of malignancy index

INTRODUCTION

This retrospective observational study explores the complex terrain of adnexal masses, which are a diverse array of uterine adnexa-derived growths encompassing the fallopian tubes and ovaries. Symptoms can originate from a variety of etiologies within this domain from benign entities like luteal cysts, ovarian cysts, and endometriosis to infectious manifestations caused by the tubercle bacillus, sexually transmitted infections, pelvic inflammatory disease and malignant origins like borderline and malignant tumors.[1,2]

The scarcity of resources in peripheral health clinics serving rural female populations impedes the necessity of prompt diagnosis and referral to specialist institutions that are equipped with necessary diagnostic, interventional, and therapeutic modalities.

The investigation of efficient diagnostic tools is driven by the realization that ovarian cancer has an incidence of 9 to 17 per 100,000 women and late diagnosis leads to an progression to advanced stages of the disease (FIGO stage III/IV) which has a constricted 5-year survival rate of 6-22%.[3,4]

Prior to surgery, it is vital to make the distinction between benign and malignant causes of adnexal masses in order to initiate the best first-line therapeutic measures. The initial evaluation is based on a thorough clinical evaluation that takes into consideration a variety of risk factors, including age, parity, family history of breast and ovarian cancer, exposure to hormone replacement therapy (HRT), pregnancy in reproductive age group and postmenopausal status.[2,5] Although the sensitivity and specificity of standard investigative approaches such as tumor markers and transvaginal ultrasonography (TVS) are limited, the Risk of Malignancy Index (RMI) becomes a potent tool for triaging due to its higher sensitivity and specificity.[6,7] RMI is calculated as a product of the menopausal status score, the ultrasonography (USG) score, and the absolute value of serum Carbohydrate Antigen 125 (CA-125).[8]

This retrospective study aimed to assess the diagnostic utility of the RMI-2 Index by analyzing its relationship to the radiological, histological, and clinical spectra. We examine the prevalence and age distribution of adnexal masses in women in the time period of two years who visit a peripheral tertiary care facility in order improve our understanding of diagnostic strategies in the clinical sphere and provide insightful information about the complex landscape of adnexal masses.

METHODS

In this retrospective observational study, after the approval by the institutional ethics committee pertinent data was acquired from the Medical Records Department (MRD) encompassing patients who presented at a tertiary care center in central Gujarat over the course of two years from June 2020 to June 2022. The study included cases of adnexal masses exclusively managed through surgical interventions within the Department of Obstetrics and Gynecology, while cases that were managed conservatively were excluded.

TVS or transabdominal ultrasonography was used to determine morphological features such as bilateral involvement, papillary or solid regions, multiple loculations, ascites, and evidence of metastases. The following tumor marker tests were performed in accordance with the clinical history and examination: CA-125, carcinoembryonic antigen (CEA), carbohydrate antigen 19-9 (CA-19-9), alpha feto protein (AFP), beta-human chorionic gonadotropin (B-HCG), and lactate dehydrogenase (LDH). Following surgical excision, the collected samples were subjected to standard processing and stained with hematoxylin and eosin for microscopic examination. For every patient, an RMI-2 score was then determined.

The USG score was calculated using five criteria: bilaterality, multilocularity, solid regions, ascites, and intra-abdominal metastases. If none of the requirements were satisfied, a score of 1 was given; if two or more criteria were met, a score of 4 was given. Premenopausal women scored a 0, but postmenopausal women defined as those who had experienced amenorrhea for more than a year or who were over 50 and had undergone hysterectomy received a 4. The absolute value of CA-125 was evaluated in blood samples, and a cut-off value of 35 was utilized to make the distinction between benign and malignant adnexal masses.

The Chi-square test was used as a nonparametric test to investigate associations between demographic, biochemical, and ultrasonographic data in people with benign and malignant adnexal masses. After performing a receiver operator characteristic (ROC) analysis to evaluate the sensitivity and specificity of RMI-2 scores, the ROC curve was produced. The sensitivity, specificity, negative predictive value (NPV), and positive predictive value (PPV) for the RMI 2 values were calculated as well. The P value of 0.05 and the 95% confidence interval (CI) was used to establish statistical significance. MedCalc ® Statistical Software version 20.113 was used for statistical analysis. Descriptive statistics (Mean with 2SD, Mode with IQR), Chi-square test, Sensitivity, specificity, NPV and PPV of RMI II and ROC Curve and LR for RMI 2 were determined.

RESULTS

A total of sixty-six patients were included in this study, and histological analysis was used to investigate the etiology of the adnexal masses. The categorization revealed 37.87% benign (25 patients), 59.09% malignant (39 patients), and 3.03% borderline cases (2 patients), with further classification based on epithelial, germ cell, and stromal origin (Table 1).

Table 1: Case distribution.

Benign	25	Borderline	2	Malignant	39
Epithelial					
Serous	14	Serous	1	Serous	28
Mucinous	2	Mucinous	1	Mucinous	5
Germ Cell					
Teratoma	4			Malignant teratoma	4
Sex-cord stromal					
Fibroma/ thecoma	5			Granulosa	2

Table 2: Age wise distribution of case.

Age (years)	Benign	Borderline	Malignant	Total
10-25	3	1	2	5
26-40	9	0	8	17
41-55	8	1	15	24
56-70	4	0	12	16
>70	1	0	2	3
Total	25	2	39	66

Table 2 highlights the age distribution and indicates that the majority of malignant tumors occur in the 56-70 years of age range. In contrast, the majority of benign tumors in our study occur before the age of 55.

The validity of the correlation between several factors and the genesis of adnexal masses was investigated. The focus was not only on clinical features including tumor size, bilateral or unilateral involvement, presence of ascites, consistency of mass, locularity, and CA-125, but also included the epidemiological factors like age, BMI, parity status, and menopausal status (Table 3).

Table 3: Distribution of parameters.

Clinical parameters	Benign (n=25) (%)	Borderline (n=2) (%)	Malignant (n=39) (%)	P-value
Age (years)				
55	20 (80)	1 (50)	25 (64)	0.7
>55	5 (20)	1 (50)	14 (36)	
BMI				
<18.5	2 (8)	0 (0)	2 (5)	0.8
19-24.5	14 (56)	2 (100)	20 (51)	
>25	9 (36)	0 (0)	14 (36)	
Parity				
0-1	10 (15.1)	1 (1.5)	3 (4.5)	0.0017
≥2	15 (22.7)	1 (1.5)	36 (54.5)	
Menopausal				
Pre	17 (25.7)	1 (1.5)	13 (19.6)	0.0066
Post	8 (12.1)	1 (1.5)	26 (39.3)	
Tumor size				
<5 cm	3 (4.5)	1 (1.5)	8 (12.1)	0.3
≥5 cm	22 (33.3)	1 (1.5)	31 (46.9)	
Laterality				
U/L	19 (28.7)	2 (3.0)	28 (42.4)	0.18
B/L	6 (9.1)	0 (0)	11 (16.6)	
Ascites				
Yes	3 (4.5)	0 (0)	21 (31.8)	0.018
No	22 (33.3)	2 (3.0)	18 (27.2)	
Consistency				
Solid	5 (7.5)	1 (1.5)	30 (45.4)	0.0001
Cystic	20 (30.3)	1 (1.5)	9 (13.6)	
Locularity				
Unilocular	19 (28.7)	0 (0)	32 (48.4)	0.3
Multilocular	6 (9.1)	2 (3.0)	7 (10.6)	
CA-125				
<35	16 (24.2)	2 (3.0)	5 (7.5)	0.00002
≥35	9 (13.6)	0 (0)	34 (51.5)	

In the context of epidemiological parameters, our evaluation revealed that there were no statistically significant relationships between age and BMI, with a balanced distribution between benign and malignant cases. Conversely, there were notable correlations between menopausal status and parity, with menopausal status was statistically significant with a P-value of 0.0066. Compared to the benign group, the malignant group showed a greater proportion of postmenopausal women. Likewise, parity status reached significance (P-value = 0.0017).

The existence of ascites and the tumor's consistency were shown to be significant parameters in the scope of USG results, as indicated by their corresponding P values. The association implies that solid tumors and the presence of ascites are indicative of malignancy. The largest tumor, more than 5 cm, was shown to be statistically significantly associated with malignant tumors. In contrast, our study's benign and malignant groups showed almost identical distributions of characteristics including locularity and laterality. CA-125 and the existence of malignancy had an association with a P value of 0.00002.

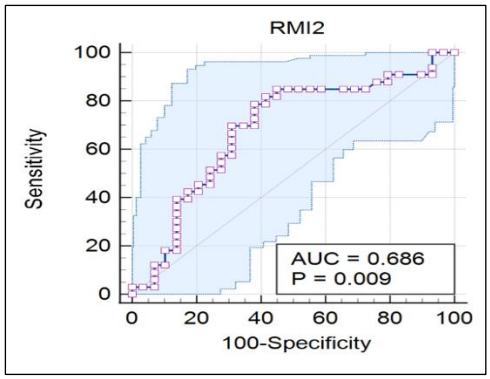

Figure 1: Receiver operating characteristic curve showing the relationship between sensitivity and specificity in differentiating between benign and malignant adnexal masses.

A Receiver Operating Curve (ROC) was plotted and offered insights into the sensitivity and specificity associated with varied RMI cut-off values (Figure 1). A cut-off value of 250 achieved a sensitivity and specificity of 85.2% (CI: 68.9-95.0) and 66.6% (CI: 47.1-82.7) respectively. Its' PPV is 74.3% (CI: 63.1-90.3) and its' NPV is 8.0% (CI: 63.1-90.3). As the PPV rises and the RMI cut-off value rises specificity increases whereas NPV and sensitivity decrease. The probability of having a malignant mass was estimated to be 1.84 at a cut-off of 250.

The distribution of benign and malignant masses varied within the sub-group of the determined RMI cut offs of 250. Patients with an RMI of <250 included 20 benign and 10 malignant cases, whereas those with RMI of >250 had 5 benign and 29 malignant (Table 4).

Table 4: Predictive value of RMI.

RMI	Benign	Malignant	Sensitivity	Specificity	PPV	NPV
<250	20	10	85.29	66.6	74.36	80.0
>250	5	29	(68.9-95.05)	(47.1-82.7)	(63.18-90.3)	(63.14-90.33)

Table 5: The sensitivity, specificity, and the likelihood ratio for malignancy given a positive or negative result for different levels of RMI.

Criterion	Sensitivity	95% CI	Specificity	95% CI	+LR	-LR
≥5	100.00	89.4 - 100.0	0.00	0.0 - 11.9	1.00	
>7	100.00	89.4 - 100.0	6.90	0.8 - 22.8	1.07	0.00
>9	90.91	75.7 - 98.1	6.90	0.8 - 22.8	0.98	1.32
>12	90.91	75.7 - 98.1	20.69	8.0 - 39.7	1.15	0.44
>16	87.88	71.8 - 96.6	20.69	8.0 - 39.7	1.11	0.59
>20	87.88	71.8 - 96.6	24.14	10.3 - 43.5	1.16	0.50
>28	84.85	68.1 - 94.9	27.59	12.7 - 47.2	1.17	0.55
>100	84.85	68.1 - 94.9	55.17	35.7 - 73.6	1.89	0.27
>119	81.82	64.5 - 93.0	55.17	35.7 - 73.6	1.83	0.33
>125	81.82	64.5 - 93.0	58.62	38.9 - 76.5	1.98	0.31
>132	78.79	61.1 - 91.0	58.62	38.9 - 76.5	1.90	0.36
>150	78.79	61.1 - 91.0	62.07	42.3 - 79.3	2.08	0.34
>224	69.70	51.3 - 84.4	62.07	42.3 - 79.3	1.84	0.49
>260	69.70	51.3 - 84.4	68.97	49.2 - 84.7	2.25	0.44
>607	57.58	39.2 - 74.5	68.97	49.2 - 84.7	1.86	0.62
>616	57.58	39.2 - 74.5	72.41	52.8 - 87.3	2.09	0.59
>920	51.52	33.5 - 69.2	72.41	52.8 - 87.3	1.87	0.67
>1288	51.52	33.5 - 69.2	75.86	56.5 - 89.7	2.13	0.64

DISCUSSION

This observational study includes cases managed over a spanning over two years at our tertiary care center that had a principal intention of appraising the efficacy of RMI-2 in distinguishing benign from malignant adnexal masses. Sixty-six consecutively admitted patients were included over this time interval, highlighting thirty-nine adnexal masses found malignant in nature upon conclusive histopathological study, along with two borderline tumors.

The first-choice imaging technique for assessing a possible adnexal tumor is USG.[9,10] A subjective pattern detection to determine malignant adnexal masses via morphological features include dimensions, composition (cystic, solid, or mixed), and laterality, presence of papillary projections, echogenicity, thick walls and septa,

abdominal metastasis and ascites. For delineating vascular features Colour Doppler flow studies are excellent additions to USG.[10-12] For complicated lesions magnetic resonance imaging (MRI) is the next imaging modality to be used, while computed tomography (CT) is employed to rule-out extraovarian pathology.[13] A notable contrast is observed of the diagnostic prowess of ultrasound, particularly among premenopausal subjects who exhibited a propensity for false positives.[14]

Other USG-based risk prediction models include the Assessment of Different NEoplasias in the adneXa (ADNEX) model, which offers a risk of malignancy probability based on three clinical variables and six ultrasound predictors, and Simple Rules (SR), which provides a binary differentiation. Both were developed by the International Ovarian Tumor Analysis (IOTA) group.[15-17] The IOTA group's ADNEX model provides the basis for the risk assessment technique employed in Ovarian-Adnexal Reporting and Data method (O-RADS). It's aim is to improving the characterization of ovarian pathology by using uniform image interpretation and reporting.[16-19]

Biochemical analysis employs the utilization of CA 125 levels, Singhal et al reported a 90% specificity and 75% sensitivity for CA 125 levels more than 35 u/ml in a recent investigation but it has a tendency to increase in a number of benign conditions, including endometriosis, benign ovarian cysts, pelvic infections, and various malignancies like carcinoma of the endometrium, fallopian tube, colon, and breast.[20,21] Human Epididymis Protein 4 (HE4) is another potential biomarker, that is used in conjunction with CA-125 in the risk of malignancy algorithm (ROMA).[22] It is found to be overexpressed in ovarian tumors, particularly in endometrioid ovarian cancer.[23] The variation observed due to smoking and contraceptive use contribute to its limitation in its ability to be a sole predictor of malignancy just like CA-125.[24]

Consequently, RMI's dependability is reinforced relative to other metrics, such as biochemical, radiological, or epidemiological, and its relative ease of use prompted our study.

RMI is a scoring system that takes into account serum CA-125 concentrations, menopausal state, and ultrasound results. RMI 1 was originally created in the 1990s by Jacobs et al.[25] Tingulstad et al in 1996 created RMI 2 and updated it in 1999 to RMI 3.[26,27] Yamamoto and colleagues added the tumor size (S) parameter and dubbed it to RMI 4.[28]

Tingulstad et al reported that RMI 2 outperformed RMI 1 at a cutoff level of 200.[26] Morgante et al demonstrated a comparable outcome, reporting that RMI 2 outperformed RMI 1 and that the difference was statistically significant for cutoff values between 80 and 250.[29] These findings correlated to our results at an RMI-2 cut off of 250 the sensitivity, specificity, PPV and NPV of our study were 85.2%, 66.6%, 74% and 80.0% respectively.

Ashrafgangooei et al utilized a cut-off level of 238 and RMI showed a sensitivity of 89.5%, a specificity of 96.2%, a PPV of 77.3%, a NPV of 98.4%.[30] Whereas Zinatossadat Bouzari et al, reported at a cut off of 250 a complementary sensitivity of 91.0% specificity 79% a contrasting PPV 39% and NPV of 98.7% whereas at a cut-off of 355 the sensitivity was 91%, specificity was 96%, PPV of 78% and NPV of 99%. In a study done by Javdekar et al, RMI-2 had a sensitivity of 70.5%, a specificity of 87.8%, at a cut-off of 250 and at a cut off of 1000 sensitivity of 58% and specificity of 97.56%.[6] A similar trend of increased specificity and decreasing sensitivity was seen at higher RMI values in our study as well (Table 5).

Recent literature by Priyanka et al highlighted RMI-4 as a better tool for triage, which mimics the findings by Yamamoto et al.[31,28] while other studies suggest that all of the four iterations of RMI are equal in their diagnostic capabilities.[32,8] Disparate findings between individual RMI iterations might exist but its utility in detecting the characteristics of adnexal masses in resource limited settings is an unequivocal observation.

Post triaging, the next step in management consists of a surgical or conservative approach. Referral to a cancer center for a complete staging by a subspecialist gynecological oncologist is recommended if the woman is deemed to be at high risk characterized by presence of high blood flow, ascites and solid components on TVS.[33] When managed in specialist facilities under the guidance of gynecologic oncologists, survival is reported to be better.[34]

The limitations of the study can be overcome with a multi-centric study involving a larger pool of participants from diverse demographic backgrounds. A larger time-frame can help identify the presenting trend of adnexal masses. Instead of a retrospective study design, a prospective approach can help ascertain the ability of utilizing RMI in daily clinical practice. Tertiary centers often receive referrals from primary and secondary care centers and hence the sample size is not truly representative of the real population. These factors along with exclusion of conservatively managed patients affect the external validity of the study.

CONCLUSION

The diagnosis accuracy of the RMI can be improved by using a multidisciplinary strategy that integrates clinical knowledge with imaging and pathology data to evaluate adnexal masses more thoroughly via collaboration between researchers, radiologists, pathologists, and physicians. An integrative approach like this upholds the principles of patient centric care. In conclusion RMI 2 is able to adequately discriminate between malignant and

benign pelvic masses. The RMI scoring system is important for triaging at peripheral centers and to decide further management and to decide if referral is required or not.

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