A Study of Risk Malignancy Index (RMI) in Adnexal masses of a Tertiary Care Hospital

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Abstract

Background: Adnexal masses are a common cause for admission of patients to Gynecology clinics, and one of the most common reasons for referral to gynecologic oncology departments for possibility of uterine or ovarian malignancies. The most prevalent type of pelvic masses is ovarian masses, which include benign cysts and tumors. To standardize and improve the pre-operative evaluation, a scoring system of Risk of Malignancy Index-3(RMI-3) as is developed. A cut off value of 200 for RMI revealed the best discrimination between benign and malignant adnexal mass, because of its high sensitivity and specificity levels. Aims and Objectives: (a)To evaluate the effectiveness of risk of RMI-3 in preoperative discrimination between benign and malignant adnexal masses. (b)To arrive at optimal cut off point of RMI-3 score for benign and malignant adnexal mass. (c) To find out the sensitivity, specificity, positive predictive value, negative predictive value and accuracy for RMI-3 score. Method: It is a prospective study conducted in Obstetrics & Gynecology Department of M.K.C.G. Medical College & Hospital, Berhampur; Odisha, India from September 2017 to September 2019 over 130 cases with adnexal masses after approval by IEC. Leading symptoms such as abdominal mass, swelling/discomfort, abdominal pain, gastrointestinal symptoms, urinary symptoms, generalized malaise and fatigue were also checked. All patients underwent routine physical examination followed by breast examination, lymphadenopathy, abdominal examination and pelvic examination. The RMI-3 for each case was calculated using the product of the ultrasound score (U), menopausal score (M) and the absolute value of serum CA-125. RMI was evaluated for sensitivity, specificity, positive predictive value (PPV), negative predictive values (NPV) and diagnostic accuracy with reference to the actual presence of a malignant or benign pelvic tumor. Results: The study included 130 cases with adnexal masses of which 85 cases (65.4%) are benign and 45 cases (34.6%) are malignant. Among all 81 cases (62.3 %) had an ultrasound score of 1 while 49 cases (37.7%) had scored 3. Of the 81 cases with ultrasound score 1, 72 cases (88.9%) had benign and 9 cases (11.1%) had malignant diseases. Of the 49 cases with ultrasound score of 3, 13 cases (26.5%) had beingn and 36 cases (73.5%) had malignant diseases. With CA-125 of 35 U/ml as cut off, 52 cases (40%) had less than 35 IU/ml and 78 cases (60%) had more than 35 U/ml. Out of 52 cases with CA-125 < 35 U/ml, 41 cases (78.8%) had benign and 11 cases (21.2%) had malignant diseases. Out of 78 cases with CA-125 > 35 U/ml, 44 cases (56.4%) had benign and 34 cases (43.6%) had malignant lesions. Out of 93 patients with RMI < 200, 11 cases (11.8%) have malignant and 82 cases (88.2%) have benign diseases. Of 37 cases with RMI > 200, 34 cases (91.9%) have malignant and 3 cases (81.%) have benign diseases. The best performance for RMI-3 was at cut-off point 225 with highest area under the ROC curve is 87% with sensitivity of 75.55%, specificity of 98.82%, PPV of 97.14%, NPV of 88.42% and an accuracy of 90.76%. RMI-3 at cut off value of 200 gives sensitivity of 75.5%, specificity of 96.4%, PPV of 91.89%, NPV of 88.17% and accuracy of 86.92%. Among all cases, 95 cases (73.1%) had RMI < 225 and out of which 84 cases (88.5%) were benign and 11 cases (11.5%) were malignant. Among 35 cases (26.9%) with RMI >225, one case (2.9%) was benign and 34 cases (97.1%) were malignant lesions (p<0.05). Among the criteria RMI-3 score > 225 has highest sensitivity, specificity, PPV, NPV and diagnostic accuracy when compared with individual parameters. **Conclusion:** RMI-3 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 or CA-125 or menopausal score.

Keywords: adnexal mass, CA-125, Malignant lesions, RMI.

Introduction

Adnexal masses are a common cause for admission of patients to gynecology clinics and one of the most common reasons for referral to gynecologic oncology departments for possibility of uterine or ovarian malignancies. The most prevalent type of pelvic masses is ovarian masses, which include benign cysts and tumors.^[1] The factors for increased risk of adnexal mass include older age, nulliparity, family history of ovarian, endometrial, or breast cancer etc.^[2] The high mortality rate of ovarian cancer among adnexal masses is due to asymptomatic and indolent growth of the tumor, delayed onset of symptoms, and lack of proper screening that results in its diagnosis at advanced stages.^[3] Currently, the conventional modalities like clinical examination, ultrasound assessment, and tumor markers assay are used to assess pelvic mass but none is alone sufficiently sensitive and specific for detecting malignancy in ovarian masses.^[4] To standardize and improve the pre-operative evaluation, a scoring system of Risk of Malignancy Index-3(RMI-3) is developed. A cut off value of 200 for RMI revealed the best discrimination between benign and malignant adnexal mass, because of its high sensitivity and specificity levels.^[5] The purpose of the present study is to assess the ability of RMI-3 scoring system in differentiating benign and malignant ovarian tumors and to compare the scoring patterns with histopathological findings.

Aims and Objectives

a) To evaluate the effectiveness of risk of RMI-3 in preoperative discrimination between benign and malignant adnexal masses.

b) To arrive at optimal cut off point of RMI-3 score for benign and malignant adnexal mass.

c) To find out the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and accuracy for RMI-3 score

Materials and Methods

It is a prospective study conducted in obstetrics & gynecology department of M.K.C.G. Medical College & Hospital, Berhampur; Odisha, India from September 2017 to September 2019 over 130 cases with adnexal masses after approval by IEC. Basing on inclusion and exclusion criteria cases were selected for study as follows: inclusion criteria: all patients having an adnexal mass diagnosed and exclusion criteria: (a) cases already diagnosed as ovarian malignancy receiving chemotherapy (b) masses arising from urinary tract and gastrointestinal tract (c)

pregnancy with its complications like ectopic, molar and post abortion. Detailed history regarding age, parity, education, menstrual status, family history of cancer, personal history of previous malignancies, symptoms and duration of symptoms were taken. Leading symptoms such as abdominal mass, swelling, abdominal pain, gastrointestinal symptoms, urinary symptoms, generalized malaise and fatigue were also checked. All patients underwent routine physical examination followed by breast examination, lymphadenopathy, abdominal examination and examination. Besides the pelvic routine investigations, CA-125 serum levels, abdominal ultrasounds findings, and menopausal status of all the cases were recorded preoperatively. The RMI-3 for each case was calculated using the product of the ultrasound score (U), menopausal score (M) and the absolute value of serum CA-125 level. Five ultrasound features suggestive of malignancy (U) were taken including (a) multilocularity (b) solid areas (c) bilaterality (d) ascites (e) metastases. Score of U was 1 if none or one of these findings was detected and a score of 3 was given if two or more of these features were present. Postmenopausal score was 3 for cases having more than one year of amenorrhea of age older than 50 years and cases that had undergone hysterectomy, all other cases who did not meet these criteria were scored as 1. The histopathological diagnosis was considered as the gold standard for defining the outcomes and RMI was evaluated for sensitivity, specificity, PPV, NPV and diagnostic accuracy with reference to the actual presence of a malignant or benign pelvic tumor. Surgical staging involved systemic exploration of the under surface of the diaphragm, liver stomach, bowel and omentum followed by biopsy. Ascitic fluid and peritoneal wash was collected in heparinised bottles for cytology. The pelvic and para aortic lymph nodes were evaluated and all enlarged lymph mode were resected followed bv infracolic omentectomy. The surgical staging was followed

by definitive surgery or debulking surgery or chemotheraphy and specimen was sent for histopathological study. The p value of < 0.05 was taken to be statistically significant. Receiver Operating Characteristics (ROC) curves of CA– 125 and RMI were plotted to determine the appropriate cut-off value for discriminating between benign and malignant adnexal masses.

Results

The study included 130 cases with adnexal masses of which 85 cases (65.4%) are benign and 45 cases (34.6%) are malignant. Maximum number of cases i.e 57 cases (43.8%) belonged to 40-59 years of age. Among the 85 benign cases, maximum cases i.e 47 cases (55.3%) are of 20-39 yrs followed by 30 cases (35.3%) of 40-59 yrs, 3 cases (3.5%) of below 20 yrs and 5 cases (5.9%) of more than 60 years. Among 45 malignant cases, 27 cases (60%) belonged to 40-59 yrs, 5 cases (11.1%) of less than 20 yrs and 4 cases (8.9%) of 20-39 yrs(Figure-I).



Figure-I: Age distribution in relation to cases The mean age of cases with malignant mass was $(47.89 \pm 14.12 \text{yrs})$ significantly higher than that of benign masses $(37.41 \pm 12.66 \text{ yrs})$ (p<0.001). Majority of cases, 86 cases (66.2%) were multipara out of which 52 cases had benign tumor and 34 cases had malignant tumor. Among the 23 nulliparous cases (17.7%), 15 cases had benign tumor and 8 cases had malignant tumor. Out of 21 primiparous cases (16.1%), 18 cases had benign tumor and 3 cases had malignant tumor (p=0.093). Adnexal mass were most commonly

seen among premenopausal women as 84 cases (64.6%). Among premenopausal cases, 68 cases(81%) had benign mass and 16 cases(19%) had malignant mass and among postmenopausal women, 17 cases (36.9%) had benign mass and 29 cases(63.1%) had malignant mass(p< 0.001)(Figure-II).



Figure-II: Menstrual Status of Study group

Majority of cases, 72 cases (55.4%) presented with pain abdomen followed by abdominal distension only in 26 cases (20%), mass abdomen in 21 cases (16.2%), mass abdomen with pain abdomen in 6 cases (4.6%), bleeding per vaginum with pain abdomen in 3 cases (2.3%) and pain abdomen with distension in 2 cases (1.5%) (Table-I).

Table No 1:	Clinical	Presentation	of Study	group
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Chief Complain	Benign	Malignant	Total
Pain Abdomen	60	12	72 (55.4%)
Abdominal Distension only	10	16	26 (20.0%)
Mass Abdomen	12	9	21 (16.2%)
Mass Abdomen + Pain Abdomen	0	6	6 (4.6%)
Abdominal Distension + Pain Abdomen	2	0	2 (1.5%)
Pain Abdomen + Bleeding per vaginum	1	2	3 (2.3%)

Among all cases, bilateral mass was found in 13 cases(10%) and out of which 7 cases(53.8%) were benign and 6 cases(46.2%) were malignant(p=0.357). Multilocular lesions were found in 58 cases (44.6%) out of which 34 cases (58.6%) were benign and 24 cases(41.4%) were malignant(p=0.146). Presence of solid components was found in 63 cases (48.5%) out of which 19 cases (30.2%) were benign and 44 cases (69.8%) were malignant(p<0.001). Ascites was seen in 31 cases (23.8%) out of which 5 cases (16.1%) were benign and 26 cases (83.9%) were malignant (p<0.001). Evidence of metastasis was found only in 4 cases (3.0%) and all of them were found to be malignant (p<0.005) (Table-II).

Table-II: USG	feature	of study	group
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USG Features	Benign	Malignant	Total	P value
Bilateral	7 (53.8%)	6 (46.2%)	13 (10%)	p=0.357
Multilocular	34(58.6%)	24(41.4%)	58(44.6%)	p=0.146
Solid Areas	19(30.2%)	44(69.8%)	63(48.4%)	p<0.001
Ascites	5 (16.1%)	26 (83.9%)	31 (23.8%)	p<0.001
Metastasis	0 (0%)	4 (100%)	4 (3.0%)	p<0.005

Among all cases, 81 cases (62.3 %) had an ultrasound score of 1 while 49 cases (37.7%) had scored of 3. Of the 81 cases with ultrasound score 1, 72 cases (88.9%) had benign and 9 cases (11.1%) had malignant diseases. Of the 49 cases with ultrasound score of 3, 13 cases (26.5%) had

benign and 36 cases (73.5%) had malignant diseases (p<0.001) (Figure-III).



Figure-III: USG scoring of Study group

Out of 52 cases with CA-125 < 35 U/ml, 41 cases (78.8%) had benign and 11 cases (21.2%) had malignant diseases. Out of 78 cases with CA-125 > 35 U/ml, 44 cases (56.4%) had benign and 34 cases (43.6%) had malignant lesions (p=0.008) (Figure-IV).



Figure-IV : Serum CA-125 level distribution among cases

Best performance for CA-125 level was obtained at 43.18 U/ml with highest AUC (75.7%) with sensitivity of 75.55%, specificity of 55.29%, PPV of 47.22%, NPV of 81.03% and accuracy of 62.30 % (Table-III).

Tuble III. Sensitivity, Specificity, II V, IVI V and IVOC IOI CIV 125						
Cut off	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	AUC	Accuracy (%)
35	75.55	48.23	43.58	78.84	0.619	57.69
43.18	75.55	55.29	47.22	81.03	0.757	62.30
50	73.33	60.0	49.25	80.09	0.667	64.61
100	53.33	84.70	64.86	77.4	0.69	73.84
143	44.44	96.4	86.95	76.63	0.705	78.46

Table-III: Sensitivity, Specificity, PPV, NPV and AUC for CA-125

The sensitivity, specificity, PPV, NPV was 75.6%, 48.2%, 43.6% and 78.8% respectively for CA-125 at cut off level of 35 U/ml in discriminating benign and malignant tumor. The distribution of individual parameters and RMI-3 in differentiation of benign and malignant adnexal masses with respective p value showed that USG score of 3 has the highest sensitivity(80%) followed by serum CA-125 level(75.6%) and menopausal score of 3(64.4%)(Table-IV). Also USG score-3 has specificity, PPV, NPV and diagnostic accuracy of 84.7%, 73.5%, 88.9% and 83.1% respectively. Menopausal score of 3 had a higher specificity (80%) and NPV (81%) but lower sensitivity (64.4%) and PPV (63.04%).

	USG	score	Menopau	isal score	CA	-125	RM	I - 3
			_		level(U/ml)		
	1	3	1	3	<35	>35	<200	>200
Benign	72	13	68	17	41	44	82	3 (3.5%)
(85)	(84.7%)	(15.3%)	(80%)	(20%)	(48.2%)	(51.8%)	(96.5%	
Malignant	9	36	16	29	11	34	11	34
(45)	(20%)	(80%)	(35.6%	(64.4%)	(24.4%)	(75.6%)	(24.4%)	(75.6%)
Total (130)	81	49	84	46	52	78	93	37
	(62.3%)	(37.7%)	(64.6%)	(35.4%)	(40%)	(60%)	(71.5%)	(28.5%)
p value	p < 0	0.001	p < 0	0.001	p = ().008	p <	0.05

Table-IV: Ultrasound Score, menopausal age, CA-125 levels and RMI-3 in adnexal mass

Out of all cases, 93 cases (71.5%) had RMI-3<200 and 37 cases (28.5%) had RMI-3 >200. Out of 93 patients with RMI < 200, 11 cases (11.8%) had malignant and 82 cases (88.2%) had benign diseases. Of 37 cases with RMI > 200, 34 cases (91.9%) had malignant and 3 cases (8.1%) had benign diseases (p < 0.05) (Figure-V).



Figure-V: Distribution of RMI-3 at cut off value of 200

RMI-3 at cut off value of 200 gives sensitivity of 75.5%, specificity of 96.4%, PPV of 91.8%, NPV of 88.1% and accuracy of 86.9% for detecting malignancy. The best performance for RMI-3 was at cut-off point 225 with highest AUC (87%) with sensitivity of 75.5%, specificity of 98.8%, PPV of 97.1%, NPV of 88.4% and an accuracy of 90.7% for diagnosing malignant lesions in current study. Among all cases, 95 cases (73.1%) had RMI < 225 and out of which 84 cases (88.5%) were benign and 11 cases (11.5%) were malignant. Among 35 cases (26.9%) with RMI >225, one case (2.9%) was benign and 34 cases (97.1%) were malignant lesions (p<0.05). Among the criteria RMI-3 score > 225 has highest sensitivity, specificity,

PPV, NPV and diagnostic accuracy when compared with individual parameters. Majority of cases, 46 cases (35.4%) undergone TAH+BSO followed by cystectomy in 41 cases (31.5%), salpingo-oophorectomy in 16 cases (12.3%), TAH+BSO+omentectomy in 12 cases(9.2%), staging laparotomy in 7 cases (5.4%), oophorectomy in 4 cases(3.1%) and cytoreductive surgery in 4 cases(3.1%). Among benign lesions, serous cyst adenoma was the commonest histopathological finding in 25 cases (29.4%) followed by dermoid cyst in 17cases (20%) and mucinous cystadenoma in 12 cases (14.1%). Among malignant tumors, papillary serous cystadenocarcinoma was the commonest histopathological finding in 15 cases (33.3%), followed by mucinous cystadenocarcinoma in 8 cases (17.8%) and serous cystadenocarcinoma in 6 cases (13.3%). Overall surface epithelial tumors were the commonest tumor in 83 cases (63.8%) followed by the germ cell tumors in 21 cases (16.2%), benign cysts in 14 cases(10.8%) and the sex-cord stromal tumors in 6 cases (4.6%).

Discussion

Benign lesions (65.4%) are more common among adnexal masses in premenopausal age whereas malignant lesions common among postmenopausal women concurring to Clarke et al (64.4%) and J H Rao et al (59%) among adnexal masses [6, 7]. The commonest age group affected was 40-59 years (43.8%) which is similar to Shintre et al.^[8] The mean age $(47.89 \pm$ 14.12 yrs) of cases with malignant mass is significantly higher than that of benign mass $(34.41 \pm 12.66 \text{ yrs})$ which is similar to Simsek et al [9]. Multiparous cases (66.2%) predominated in current study which is similar to Shintre et al(73.4%) but Nahar S et al found no association between parity and pelvic mass.^[8,10] Most common presentation was pain abdomen (55.4%), concordance to Zarchi M et al (53.5%).^[11] Presence of solid areas, ascites and metastasis showed significant correlation with malignancy (p<0.05) which is agreed with Priyanka et al(solid areas, ascites and metastasis found in 94.5%, 65.4% and 67.2% respectively among malignant conditions).^[12]

Malignancy is common among the women with ultrasound score of 3(73.5%) as compared to score of 1(11.1%) which is similar to Ashrafgangooei et al (p<0.05)(Table-V).^[13] Ultrasound score of 3 had the sensitivity of 80%, specificity of 84.7\%, PPV of 73.5\%, NPV of 88.9% and accuracy of 83% in detecting malignant lesions is agreement with Vasudevan et al (sensitivity:83.3%, specificity:78.2%, PPV:54.5\%, NPV: 93.8 and accuracy:23.5%).^[14] Kestane et al also found that ultrasound score has

sensitivity of 100% and specificity of 65% among malignant tumors.^[15]

Table-V:	Comparison	ı of	benign	and
malignant	<u>mass on ultra</u>	sound	score	

	Benign	Malignant	Margina l Row Totals
US	72 (52.96)	9 (28.04)	Q 1
Score-1	[6.84]	[12.93]	01
US	13 (32.04)	36 (16.96)	
Com 2			49
Score-2	[11.31]	[21.37]	
Margina			130
l Column	85	45	(Grand
Totals			Total)

Current study revealed that malignancy is common among postmenopausal woman (63.1%) which is similar to Terzic M et al (64.4%) (p<0.5)(Table-VI).^[16] Menopausal score of 3 had a higher specificity (80%) and NPV (81%) but lower sensitivity (64.4%) and PPV (63.04%) for malignancy which is similar to S K Dora et al (sensitivity: 57.9%, specificity: 84.2, PPV: 81.6%, NPV: 62.3.^[17] In contrast, J H Rao et al reported that postmenopausal score of 3 have higher sensitivity (77.36%) and PPV (78.55%) but lower specificity (62.07%) and NPV (60%).^[7]

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	Benign	Malignant	Marginal Row Totals			
Pre menopausal	68 (54.92) [3.11]	16 (29.08) [5.88]	84			
Post menopausal	17 (30.08) [5.69]	29 (15.92) [10.74]	46			
Marginal Column Totals	85	45	130 (Grand Total)			

Table-VI:Comparisonofbenignandmalignant mass on menopausal score

The serum CA-125 levels ≥35 U/ml had a sensitivity of 75.6%, specificity of only 48.2%, PPV of 43.6% and NPV of 78.8% for malignancy. Best performance of serum CA-125 was obtained at cut off of 43.18 U/ml with highest AUC (75.7%) having sensitivity of 75.6%, specificity of 55.29%, PPV of 47.22% and NPV of 81.03%, concordance to Akturk et al (75%).^[18] The RMI-3 at cut off value of 200 gives sensitivity of 75.5%, specificity of 96.4%, PPV of 91.8%, NPV of 88.1% and accuracy of 86.9% for malignancy, coinciding detecting with Manjunath et al (PPV of 93%), Enakpene et al (NPV of 90%) and Geomini et al (sensitivity :78% and specificity :87%).^[19, 20, 21] The best performance obtained for RMI-3 was at Cut-off point 225 with highest AUC(87%) having high sensitivity of 75.5%, specificity of 98.8%, PPV of 97.1%, NPV of 88.4% and accuracy of 90.7% which is in agreement with Suchitra et al (sensitivity of 86.67 %, specificity of 88.37 %, PPV of 83.87% and NPV of 90.48%).^[22] The commonest benign condition was serous cystadenoma(29.4%) and the commonest malignant tumors was papillary serous cystadenocarcinoma (33.3%) which is similar to Shintre et al where serous cystadenoma was commonest in benign lesions (24.49%).^[8]

Conclusions

Malignant adnexal mass was more common in postmenopausal women. Majority of women were presented with pain abdomen followed by mass abdomen with pain abdomen, abdominal distension, mass abdomen and bleeding per vaginum with pain abdomen. Currently, a combined diagnostic modality has come to practice in form of RMI-3. RMI-3 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 or CA-125 or menopausal score.

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