ORIGINAL RESEARCH PAPER

Radiodiagnosis

"THE ROLE OF USG(RMI) IN PREOPERATIVELY CLINICALLY DIAGNOSED OVARIAN MASS FOR MALIGNANCY PREDICTION"

KEY WORDS: RMI, CA-125, adnexal mass, ovarian mass, malignancy index

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ABSTRACT

RMI is simple, valuable, highly reliable and clinically applicable in pre-operative evaluation of ovarian mass. RMI is very useful in preoperatively differentiation of malignant and benign lesion and diagnosis of ovarian malignancy, which helps in appropriate management by counselling patient and relatives regarding the possible diagnosis, planning treatment in the form of type of surgery, route and mode of surgery. The present study demonstrated that RMI was a better estimate in diagnosing ovarian mass with high risk of malignancy. 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 gynaecologic departments.

INTRODUCTION

Pre-operative knowledge regarding the nature of ovarian mass ids necessary so as to plan surgery. Risk malignancy index (RMI) is a simple scoring system based on three factors CA-125 levels, USG score and menopausal status. It is very useful in predicting the malignant ovarian mass. It is also useful in differentiating malignant from benign ovarian mass. In most of the cases, the ovarian tumors are diagnosed at a later stage since incidence of onset and progression of this tumor makes early diagnosis difficult.

It is of particular importance to establish accurate preoperative diagnosis for adnexal masses. Reliable recognition of benign masses would reduce the number of redundant surgeries for asymptomatic benign lesions. Ovarian cancer (OC) is the most fatal of all gynaecologic malignancies in women. Optimal cytoreductive surgery is the most significant prognostic factor in the management of OC[1,2]. In the event of high index of suspicion for ovarian cancer, patients should undergo surgery in tertiary care units where optimal cytoreductive surgery could be performed[3].

The most efficient and wellknown screening method includes evaluation of CA125 and then ultrasound in case of abnormal results of CA125. The survival rate is related to the stage of the disease at the diagnosis[4]. In patients diagnosed with advanced stage III-IV ovarian cancer, the 5-year survival rate is about 30%, whereas in those diagnosed at an early stage the 5-year survival rate is about 90%[5]. Therefore it seems worthwhile to detect ovarian cancer at an early stage[6]. A cut-off value of 35U/mL yields 83.1% sensitivity but low specificity (39.3%)[7]. Menopausal status provides limited information about the nature of the adnexal masses. Menopausal status yields 55% sensitivity and 80% specificity in differentiating benign from malignant adnexal masses[8]. Ultrasonography (USG) is the most commonly performed imaging modality used to evaluate pelvic pathologies and adnexal masses[9]. USG provides 91% diagnostic accuracy in adnexal masses depending on the structure pattern of the mass[10].

There is a significant difference in management of a malignant tumour which may require radical surgery, chemotherapy, counselling regarding the disease preogression and costs involved where as benign adnexal mass may simply manage with cystectomy or laparotomy. This is adequate to signify the importance of pre-operative determination of the nature of adnexal mass for optimal and appropriate primary treatment. Otherwise results in inevitably in some patients having suboptimal oncoreductive surgery and others being understaged with attendant risk of undertreatment. Though there are many advanced models like ADNEXA, IOTA models for assessment risk of ovarian malignancy, but these new models need advanced machine, experienced radiologist. RMI is simple, valuable, highly reliable and clinically applicable in pre-operative evaluation of ovarian mass. RMI is very useful in preoperatively differentiation of malignant and benign lesion and diagnosis of ovarian malignancy, which helps in appropriate management by counselling patient and relatives regarding the possible diagnosis, planning treatment in the form of type of surgery, route and mode of surgery. This is especially helpful in pheripheral hospitals for timely referral.

OBJECTIVES:

1. To evaluate the Risk of malignancy (RMI) in pre-operatively clinically diagnosed ovarian mass.
2. To determine the validity of individual parameter of RMI.
3. To correlate the RMI with histopathology.
4. To compare the validity of individual parameter in risk of malignancy index.

MATERIALS AND METHODS

It was an observational study conducted at our tertiary care hospital for the duration of 2 years from October 2018 to September 2020.

Inclusion criteria

1. Women with clinically restricted ovarian mass of any age group
2. For premenopausal women, criteria for ovarian masses are its size more than 8 cm and for postmenopausal women size more than 5 cm.
3. Postmenopausal is defined as more than 1 year of amenorrhea or women who underwent hysterectomy (surgical menopause)

Exclusion criteria

1. Patients who were unfit for surgery and did not undergo exploratory laparotomy for the same.
2. Women having ovarian tumour with other conditions like endometriosis, fibroid, PID, concurrent malignancy.
3. If intraoperatively any other mass than ovary found also excluded from the study.

Patients with clinically diagnosed ovarian mass admitted in department of obstetrics and gynaecology, RIMS, Jharkhand for laparotomy, after fulfilling the inclusion and exclusion criteria are included in the study. The demographic data, history and examination finding written in the case sheet, CA-125 levels were noted in data sheet. CA-125 levels >200 IU/ml in premenopausal and >35IU/ml in postmenopausal women

were considered as high risk for malignancy. Ultrasound was done in our department of radiology, RIMS,Jharkhand. Ultrasound scoring of the RMI was based in one point for each of the following- bilateral lesion, multilocular cyst, evidence of solid areas, evidence of metastasis, presence of ascites. For RMI USG score, U=0 for ultrasound point 0, U=1 for ultrasound point of 1, U=3 for ultrasound point of 2 or above. The scoring was considered with recent USG (within 2 weeks from the day of surgery). RMI was calculated for each patient by multiplying the USG score, menopausal score and serum-125 level value. RMI- U x M x CA-125. Score less than 200 was considered as low risk and more than 200 as high risk. After laparotomy the histopathology reports were followed up and the outcome was defined as benign and malignant and histopathological reports were analyzed for final correlation with ultrasound findings, CA-125 levels and menopausal status. RMI was evaluated for sensitivity, specificity, positive predictive value, negative predictive value with reference to the actual presence of benign or malignant tumour.

RESULTS AND OBSERVATIONS

Total number of patients included in our study was 101.

Table no.1 Distribution according to the demographic data

S.N	Demographic parameter		F	%
1	Age		Mean age 34±12 years	
2	Parity	Nullipara	12	11.89
		Para 1	16	15.84
		Para 2	40	39.60
		Para 3 & above	33	32.67
3	Socioeconomic status	Upper	8	7.92
		Upper middle	10	9.91
		Lower middle	25	24.75
		Upper lower	41	40.59
		Lower	17	16.83
4	Residence	Urban	41	40.59
		Rural	60	59.41

In our study, the mean age was 34±12 years, majority of them were second para women, 40.59% belonged to upper lower socioeconomic status and 59.41% of them hailed from rural area.

Table no.2 Distribution according to RMI index and its individual parameters

S.N	Parameters of RMI		Frequency	Percentage
1	**Serum CA-125 levels IU/ml**			
	Premenopausal (61)	<200	59	96.72
		>200	02	3.28
	Postmenopausal (40)	<35	03	7.5
		>35	37	92.5
2	**Menopausal status**			
	Premenopausal status		61	60.40
	Postmenopausal status		40	39.60
3	**USG score**			
		Premenopausal (61)	Postmenopausal (40)	Test chi-square 4.9417, Degree of freedom 2	P value <0.001
	0	06 (9.84%)	0 (0%)		
	1	49 (80.32%)	7 (17.5%)		
	3	6 (9.84%)	33(82.5%)		
4	**RMI score**			
	<200		61	60.40
	>200		40	39.60

60.4% were premenopausal women and 39.6% were postmenopausal women. 96.72% of the premenopausal women had CA-125 levels <200 and 3.28% had >200 IU/ml. Amongst the postmenopausal women only 7.5% had CA-125 levels <35 IU/ml and 92.5% had >35 IU/ml. None of the postmenopausal women had USG score 0 and majority 82.5% of postmenopausal women had score 3. 80.3% of the premenopausal women had score 1. 60.4% had RMI score <200 and 39.60 % had RMI score >200.

Table no. 3 Correlation of histopathological report with the RMI parametres

S.N	Correlation with HPE report	F	%
1	**Histopathological report**		
	Benign	66	65.35
	Malignant	35	34.65
2	**Correlation of HPE report with menopause status**		
	Menopausal status	Benign in HPE	Malignant in HPE
	Postmenopausal(40)	16 (40%)	24 (60%)
	Premenopausal (61)	50 (81.96%)	11 (18.04%)
3	**Correlation of HPE report with CA-125 levels**		
	CA- 125 Levels	Benign in HPE	Malignant in HPE
	Premenopausal with <200(59), postmenopausal with <35(03)	55 (88.70%)	7(11.2%)
	Premenopausal with >200 (02), postmenopausal >35 (37)	11 (28.20%)	28 (71.80%)
4	**Correlation of HPE report with USG score**		
	USG score	Benign in HPE	Malignant in HPE
	3 (39)	11 (28.2%)	28 (71.8%)
	0 0r 1 (62)	55 (88.7%)	7 (11.3%)
5	**Correlation of HPE report with RMI**		
	RMI score	Benign in HPE	Malignant in HPE
	<200 (61)	57(93.44%)	4 (6.56%)
	>200(40)	9 (22.5%)	31(77.5%)

According to histopathological reports, 64.35% had benign tumours. 60% of the postmenopausal women had malignant tumours and 81.96% had benign tumours. Those who had CA-125 levels less than the threshold, 88.70% had benign tumours and only 111.2% had malignant tumor. 71.8% of the patients with USG score 3 had malignant tumors and only 11.3% had malignant tumors in those who had USG score 0 or 1.

Amongst those who had RMI score <200, 93.44% had benign tumors and 77.5% of the patients with RMI >200 had malignant tumors

Table no.4 Comparitive validity of individual parameter incorporated in RMI with RMI as an aggregate score

Statistical parameter	Menopausal status	CA-125 levels	USG score	RMI
Sensitivity	71.64	80	80	85.71
Specificity	60.00	82.08	83.88	85.07
PPV	77.41	70.00	71.79	77.5
NPV	47.50	88.78	88	91.93
Accuracy	67.64	81.08	82.58	82.29

Table no.4 shows the validity of individual parameter incorporated in RMI, USG score alone has accuracy, specificity, negative predictive value comparable with those of RMI.

DISCUSSION

As being the basic components of RMI scales, serum CA-125 levels and positive findings on USG show extensive variability depending on numerous factors and this seems to be affecting the reliability of RMIs. In a study conducted in Thailand, Moolthiya et al[11] used a cut-off value of 200 and found lower sensitivity rates for RMI. CA125 was first described by Bast et al (1981) and found elevated levels in 80% of epithelial ovarian cancers. They stated that 35 IU/mL was a threshold value for CA125 and afterwards many studies related CA125 were made in preoperative diagnosis of an adnexal mass[12]. In our study when 35 IU/mL was taken as a cutoff level for CA125, sensitivity and specificity was 78.6% and 63.5% respectively. ROC curve analysis for CA125 provided maximum Youden index at level of 79.97. And

sensitivity, specificity, PPV and NPV were calculated in order of 66.7%, 87.2%, 80.8%, 76.4% for this value. But serum CA125 can be elevated in various conditions including benign diseases not only malignancies, chronic inflammation, during menstruation and its predictive role in malignancies was singly limited. In a study[13] we found sensitivity 73.5%, specificity 97.1%, PPV 95.3% and NPV 82% by using RMI of more than 200. In our study sensitivity was 85.71%, specificity was 85.07% ,NPV was 91.93%, accuracy was 82.29%.

Ultrasound score (U) was obtained from data of morphologic findings on ultrasound. Sensitivity, specificity, PPV and NPV for U=3 (positive morphologic findings 2-5) was 53.3%, 95.5%, 90.6%, 71.9%, respectively in the study conducted by Hakkii et al[13]. Specificity and PPV for U were higher than the values reported in the literature like menopause score[14,15,16,17].

In a systematic review of 109 studies including 21750 women with adnexal masses consisted of 83 different prediction models. RMI was the best predictor and when 200 were used as the cutoff level, the pooled estimate for sensitivity was 78% for a specificity of 87% [18]. Many studies conducted in Asian and Pacific countries have reported different cut-off values as was the case in our study. We think that it is difficult to determine universally accepted cut-off values for RMIs for common use around the globe.[13]

CONCLUSION

RMI is simple, valuable, highly reliable and clinically applicable in pre-operative evaluation of ovarian mass. RMI is very useful in preoperatively differentiation of malignant and benign lesion and diagnosis of ovarian malignancy, which helps in appropriate management by counselling patient and relatives regarding the possible diagnosis, planning treatment in the form of type of surgery, route and mode of surgery. The present study demonstrated that RMI was a better estimate in diagnosing ovarian mass with high risk of malignancy and subsequent guiding the patients to gynecological oncology centres for suitable and effective surgical interventions. Compared with individual parameters of RMI i.e, USG 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.

Conflict of interest- none

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