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

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ABSTRACT

Objectives: To evaluate the diagnostic accuracy of Risk of Malignancy Index (RMI) in discriminating between benign and malignant adnexal masses taking histopathology as the gold standard.

Study Design: Validation study.

Place and Duration of Study: The study was done at the department of Obstetrics & Gynaecology, Government Lady Aitchison Hospital, Lahore from January 2009 to July 2009.

Patients and Methods: Total 60 patients were included in this study. Risk-of-malignancy Index level (RMI) < 200 was taken as benign and RMI >200 was taken as malignant. Histopathology report was followed after surgery.

Results: Mean age of the patients was found to be 41.03 ± 8.59 years. The results of RMI were compared with the histopathology with report at histopathology, 91.7% patients had benign masses and 8.3% patients had malignant masses. At RMI, 88.3% patients had benign masses and 11.7% patients had malignant masses. While RMI findings were confirmed with diagnosis made on histopathology the sensitivity, specificity and diagnostic accuracy were found to be 100%, 96.3%, 96.6%, respectively. Positive and negative predictive values of RMI were 71.4%, and 100%, respectively.

Conclusion: RMI is an appropriate tool for diagnosing adnexal masses with high risk of malignancy and referring to specialist gynecological centers for suitable surgical operations.

Keywords: Adnexal masses, Benign, Malignant, RMI.

INTRODUCTION

The term adnexa is derived from the pleural form of the Latin word meaning 'appendage'. The adnexa of the uterus include the ovaries, fallopian tube and the paraovarian tissue. Presence of an adnexal mass presents a diagnostic dilemma[1]. The differential diagnosis is extensive with most masses representing a benign process. However its essential to discriminate between benign and malignant masses because ovarian cancer mostly presents with no or minimal symptoms and nothing short of complete surgery by clinicians with specialized training and experience in managing ovarian malignancy offers survival benefit to these patients. While on the other hand, it is highly desirable and logical to avoid unnecessary diagnostic procedures, including extensive surgery with a cosmetically undesirable scar , and anxiety in women with asymptomatic, benign conditions. A considerable amount has been written attempting to use ultrasound to differentiate benign from malignant adnexal masses with accuracy rates ranging from 50 to 98%[2]. The clinical relevancy of the serum CA 125 antigen level in assessing gynecological malignancy has been well established, particularly in ovarian cancer. However, cases have been reported in literature of patients with benign diseases who have exhibitied extremely high level of CA 125. Risk of malignancy index (RMI) proposed by Jacobs et al is a simple scoring system incorporating basic sonographic parameters, serum cancer antigen 125 (CA-125) levels, and menopausal status[3].

RMI = U (ultrasound score) x M (menopausal status) x serum CA 125

U = Ultrasound Morphological score, a score 1 is given for each abnormal findings (multilocular cyst, evidence of solid areas, evidence of metastasis, presence of ascites, bilateral lesions). Maximum score is 3, a score of 0 for no finding, a score of 1 for 1 finding, 2 for 2 findings and 3 for 3 or more finding M = 3 for

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all post menopausal women, M=1 for pre menopausal women and CA 125 = serum CA 125 measurement in u / ml[4].

RMI developed by Jacobs et al[5] for distinguishing benign and malignant pelvic masses pre-operatively at a cut-off level of 200 had a sensitivity of 85.4% and a specificity of 96.9%. Davis et al[6] found a sensitivity of 87% and specificity of 89% for this index. Tingulstad et al[7] found a sensitivity of 71% and specificity of 96% for this RMI at cut-off level of 200[7]. Due to limitation of clinical impression and sonographic finding to predict ovarian malignancy, it is not surprising that gynecologists may detect an unsuspected ovarian malignancy.

Intraoperatively RMI is a scoring system that can predict ovarian malignancy thereby improving the chance of better preoperative counseling, better preoperative preparation and where appropriate referring the patients to a specialized center.

PATIENTS AND METHOD

This validation study was carried out at the department of Obstetrics & Gynaecology, Government Lady Aitchison Hospital, Lahore from January 2009 to July 2009. Patients of age 30 to 70 years, with adnexal masses on ulrasonography, patients admitted for scheduled surgical exploration of adnexal mass and histopathological diagnosis were included in the study. Patients with a known adnexal malignancy on histopathology were excluded from the study. Total 60 cases were included in the study.

Patients admitted in the gynae ward through OPD fulfilling the inclusion criteria were included in the study after taking an informed consent and assurance that their confidentiality will be maintained. Demographic information like name, age and address was noted.

They were categorized as postmenopausal or premenopausal and appropriate score was given according to criteria mentioned in the introduction.

Blood sample was obtained and sent for assay of Serum CA-125 from Cenum Laboratory, Mayo hospital Lahore. The value obtained in the test result was noted.

Ultrasound of each patient was done at Lady Aitchison Hospital and score was given according to criteria mentioned in the introduction. RMI was calculated using the equation as mentioned in the introduction where RMI <200 was taken as benign and RMI ≥ 200 was taken as malignant.

After surgery, specimen was sent to Pathology laboratory, Mayo Hospital Lahore and histopathology report was followed. Benign masses were: simple cyst, endometriotic cyst, tubo-ovarian abscess, dermoid cyst, cystadenoma, cystadenofibroma, benign mucinous tumor, endometrioid and clear cell adenofibroma. Malignant masses were: epithelial, germ cell and sex-cord stromal tumors.

Data was entered and analyzed by SPSS 10. Descriptive statistics were used to describe the results. Reviewing the histopathological diagnosis of surgical specimen, using RMI cut-off value of 200, the sensitivity, specificity, positive predictive value and negative predictive value and accuracy through 2x2 table using histopathology as gold standard were calculated.

RESULTS

In this study, 60 patients were included. Mean (SD) age of the patients was 41.03 ± 8.59 years. Among 60 patients, 66.7% cases were between 30-40 years of age. 20% cases were between 41-50 years, 6.7% cases were between 51-60 and 6.7% cases were more than 60 years of age.

Out of 60 patients, 13.3% cases were in postmenopausal and 86.7% cases were premenopausal age groups.

Ultrasonographic features indicative of malignancy were absent in 48.3% cases. 35.0% cases had at least one feature and 16.7% cases had 2 features .

Serum CA125 value was <35 units / ml in 83.3% cases while it was > 35 units / ml in 11.7% cases. RMI was <200 in 88.3% cases and was ≥200 in 11.7% cases.

The results of RMI were compared to the gold standard histopathology reports. At histopathology, 91.7% cases had benign masses and 8.3% cases had malignant masses (table).

Table-: Comparison of risk of malignancy index (RMI) versus histopathology (n = 60)

RMI	Histopathology (Gold Standard)		Total
	Malignant	Benign	
Malignant (>200)	5 (TP)	2 (FP)	7
Benign (<200)	0 (FN)	53 (TN)	53
Total	5	55	60

TP=True positive, FP=False positive, FN=False negative, TN=True negative

While RMI findings were confirmed with diagnosis made on histopathology the sensitivity, specificity and diagnostic accuracy were found to be 100%, 96.4%, 96.7%, respectively.

Positive predictive value and negative predictive value of RMI were 71.4%, and 100%, respectively.

DISCUSSION

The accuracy of diagnostic tests used to evaluate an adnexal mass is of great concern to practicing gynecologists. In the pre-operative assessment of adnexal mass, the major diagnostic tools are still clinical impression and ultrasound examination. However, due to limitation of clinical impression and sonographic finding to predict ovarian malignancy, it is not surprising that gynecologists may detect an unsuspected ovarian malignancy intraoperatively. Often an improper incision is made, the bowel is not adequately prepared or the surgeon is confronted with the need to perform an unplanned cytoreductive surgery.

A scoring system that predicts ovarian malignancy can improve the chance of better preoperative counseling, better preoperative preparation and where appropriate referring the patients to a specialized center.

Subsequent to introduction of RMI[6], the same research group who introduced RMI , had re-evaluated their diagnostic method in a new group of patients admitted for pelvic masses and confirmed the sensitivity and specificity of RMI and its priority compared to the individual criteria[5].

Adnexal masses can be of ovarian, tubal, or paratubal origin and can be physiologic, functional, neoplastic (benign or malignant), inflammatory / infectious, or pregnancy-related. In addition, other pelvic structures or pathologies may be mistaken for adnexal masses, including duplicated uteri in mullerian anomalies, pelvic kidneys, or peritoneal inclusion cysts. It is important that primary care providers understand the causes of and treatment options for adnexal masses, not only so that significant pathology can be referred and treated surgically when indicated, but also that expectant management or medical treatment can be offered when appropriate to avoid potentially unnecessary surgery with its inherent risks and sequelae[8].

There are two main clinical routes by which an adnexal mass may be detected:[8] women with symptoms may have an adnexal mass detected as part of their evaluation for those symptoms, either by physical exam or radiographic imaging;[14] the mass may be detected during bimanual pelvic examination or radiologic imaging as part of a routine health maintenance examination.

Despite the recent advances in the imaging technology, the current clinical use of sonography with or without the aid of color Doppler, combined with the serum markers is not always adequate to distinguish between benign, borderline and malignant ovarian tumors[9].

The occurrence of borderline (low malignant potential) ovarian masses is 10–20% of all ovarian epithelial tumors and is mainly diagnosed in young women[10]. More

importantly, it has been described that in preoperatively selected patients with adnexal cystic masses without sonographic evidence of thick septa, internal wall papillae, or solid components, the rate of laparoscopically discovered adnexal cysts with intracystic papillary projections was 5% of which 14% were borderline tumors[11].

Adnexal masses were found in females of all ages, fetuses to elderly. These masses may be symptomatic or discovered incidentally. Diagnosis of adnexal mass in female patients presents diverse possibilities. They range from ectopic pregnancy requiring immediate surgery to ovarian malignancy requiring planned surgery or appropriate drug therapy[12].

Age is the most important factor determining malignancy. In premenstrual and post-menopausal women the presence of an adnexal mass should be considered abnormal and must be promptly evaluated[12]. Most adnexal masses are in reproductive age women are benign. The data evaluated in present study showed that 66.6% cases were between 30-40 years of age.

In present study, RMI findings depicted the sensitivity, specificity and diagnostic accuracy of 100%, 96.3%, 96.6%, respectively.

In a study by Ulusoy et al, the RMI showed sensitivity 76.4%, specificity 77.9%, PPV 65.9%, NPV 85.5% with 79.4% correct diagnosis rate[15].

The results are comparable to those of the study of Pradhan et al who found that RMI Index, had a sensitivity of 95% and specificity of 94%[16].

The specificity of our results is comparable to that of Jacobs et al[5]. His study for distinguishing benign and malignant pelvic masses pre-operatively at RMI cut-off level of 200 had a sensitivity of 85.4% and a specificity of 96.9%[5]. Davis et al found a sensitivity of 87% and specificity of 89% for this index[6]. Tingulstad et al found a sensitivity of 71% and specificity of 96% for this RMI[7].

In current study, the positive predictive value was found to be 71.4% and the negative predictive value was found to be 100%. Obeid at et al found that the RMI gave a positive predictive value of 96%, and negative predictive value of 78%[16]. In our study the diagnostic accuracy was 96.6%. This was similar to that obtained by Pradhan[22].

CONCLUSION

The risk-of- malignancy index is a reliable tool and provides a quantitative assessment of the risk of malignancy and can be used to discriminate between benign and malignant disease. Its application in clinical practice would provide a rational basis for specialist referral of patients with malignant disease before diagnostic surgery.

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