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Original Research Paper

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"EVALUATION OF RISK OF MALIGNANCY INDEX AS PREOPERATIVE DIAGNOSIS OF OVARIAN MASS IN A TERTIARY CARE HOSPITAL"

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ABSTRACT

Background: There is no adequate preoperative method for differentiating between benign and malignant pelvic masses. **Subjects and Methods:** Out of 46 ovarian masses included in the study, 38 (82.6%) were benign and 8 (17.4%) were malignant. **Results:** Out of 46 cases, 33(71.7) were premenopausal and 13(28.3) postmenopausal. 5 out of 13 malignant cases were seen in postmenopausal group. The mean value of preoperatively determined CA125 serum levels of the patients with benign cases was 27.3 u/ml, and those with malignant cases was 547.2u/ml. **Conclusion:** RMI was found to be valuable, reliable, and applicable method in the primary evaluation of patients with pelvic masses.

KEYWORDS : Benign, Malignant, RMI and CA-125.

INTRODUCTION

There is no adequate preoperative method for differentiating between benign and malignant pelvic masses. Ovarian cancer remains the third most frequent gynecological neoplasm and corresponds to the highest mortality rate in developed countries.[1] The most prevalent type of pelvic masses is ovarian masses, which include cysts and tumors. The size of the mass, its mobility, consistency, shape, possible internal aqueous component, and associated pain are helpful features for diagnosis of the nature of the mass.[2] Ovarian mass is the frequent cause of gynaecological consultation and are often detected during imaging studies or exploratory surgery for acute abdomen.[3] They occur across different age groups and could result from benign to malignant. Ovarian masses, however benign in 90% of cases, are the fourth most common gynecological causes for hospitalization. The differential diagnosis of ovarian mass varies from functional cysts to benign and malignant tumors.[4] Up to 24% of ovarian tumors in premenopausal woman is malignant and upto 60% are malignant in postmenopausal women. They have lowest 5-year survival rate (30-50%) among gynecological cancers. correct preoperative diagnosis is crucial and remains a challenging issue for gynecologists.[5] On the other hand, identifying women with benign pathology is important in order to avoid unnecessary morbidity as well as unnecessary costs. Preoperative evaluation of ovarian mass is rather complicated process as the differentiation of benign and malignant mass is difficult.[6] However, when evaluated individually the efficacy of ultrasound, demographics and biochemical values are incapable of distinguishing benign from malignant tumors.[7] The rate of malignancy in pelvic masses of premenopausal women is approximately 24% while in post-menopausal women it increases to more than 60%, mostly from uterine or ovarian cancer. Unfortunately, most of these masses are asymptomatic or considered unimportant, leading to a delay in admission, difficulty of curative surgery, and ultimately decreased survival. In retrospective studies published during the past decade, the importance of estimating the risk of malignancy as an effective method for differentiation of malignant vs. benign masses was emphasized in an attempt to achieve early preoperative diagnosis by using a combination of serum CA125 level, menstrual status, and ultrasound findings (U), the latter being composed of five characteristics (cystic multilocular lesion, solid lesion, bilateralism, ascites, and metastasis).[8] The risk of malignancy index was developed for referral of relevant patients to gynecologic oncologic centres. It has been suggested that decisions on how to manage women with an ovarian mass be taken on the basis of the Risk of Malignancy Index by the Royal College of Obstetricians and Gynecologists. [9]

SUBJECTS AND METHODS

The present study was conducted in the Department of Obstetrics and Gynaecology at World College of Medical Sciences & Research and Civil Hospital, Jhajjar during the period from November 2018 to October 2020. Total of 46 women were included in the study. The research protocols were ratified by the Ethics Committee at World College of Medical Sciences & Research and Civil Hospital and informed consent was obtained from all the subjects. Women in the age group of 26 to 76 years presenting with at least one persistent ovarian mass that was selected for surgical intervention were included in the study. Following women were excluded from the study, pregnant women with ovarian masses and patients who are diagnosed with ovarian malignancy before and who are on treatment. At the time of registration a standardized history was taken including the patient's age and menopausal status, information on personal history of ovarian and breast cancer, number of first-degree relatives with ovarian or breast cancer, current hormonal therapy and previous gynecological surgery. Preoperative menopausal status, ultrasound findings and serum CA-125 levels were noted. Postmenopausal status was defined as more than one year of amenorrhea or age older than 50 years in women who had undergone hysterectomy. All other women were considered premenopausal. The ultrasound was performed transabdominally by a 7.5-MHz transducer (Philips HD machine). A standardized approach was used to carry out ultrasonography in all the women. A score was assigned for the presence of following ultrasound features suggestive of malignancy: multilocularity, solid areas, bilateral lesions, ascites and intraabdominal metastases. A score of one was assigned for the presence of each ultrasound feature. A total ultrasound score (U) was thus calculated for each patient. In the event of multiple masses, the mass with the most complex used ultrasound morphology was collect information on tumor characteristics for statistical analysis. When masses with similar morphology were observed the larger of the two masses or the one most easily visible by ultrasonography was included. Serum samples were collected. Peripheral venous blood samples of 5ml were drawn preoperatively from each patient observing universal precautions. The blood was centrifuged at 2500 rpm for 5 minutes. CA-125 was assayed in the serum by electro chemiluminescence immunoassay.

Statistical Analysis

Data was analyzed by Pearson's Chi square test. The x-test was used to test differences in distribution of age, menopausal status, ultrasound score. All statistical analyses were done using Statistical Package for Socla Sciences (SPSS) 22. The histopathological diagnosis was considered as the gold standard for defining the outcomes. Tumors were classified as benign, borderline or invasive. Surgery was

performed by laparoscopy or laparotomy according to the surgeon's judgment, and the subsequent tissue examination was performed at the Department of Pathology, World College of Medical Sciences & Research and Civil Hospital. In case of a borderline or invasive tumour, surgical stage was recorded according to the criteria recommended by the International Federal of Gynecology and Obstetrics.

RESULTS

Total of 46 ovarian masses were included in the study, 38 (82.6%) were benign and 8 (17.4%) were malignant. The mean age of the patients with benign lesions was 38.24±12.51years, those with malignant masses was57.78±16.46 years. Out of 46 cases, 33(71.7) were premenopausal and 13(28.3) postmenopausal. 5 out of 13 malignant cases were seen in postmenopausal group. The mean value of preoperatively determined CA125 serum levels of the patients with benign cases was 27.3 u/ml, and those with malignant cases was 547.2u/ml. Multilocular cysts were seen in 76.2% of malignant ovarian tumour in comparison to 46.3% of benign tumours. 73.2% of the malignant ovarian were found to have solid areas in contrast to only 22.3% of benign tumours. Only 2 of the 8 malignant masses were bilateral, among benign lesions 4 were bilateral. Ascites was present in 43.2% of malignant tumour but it was absent in benign tumour. 1 out of 8 malignant cases had distinct metastasis, none in benign cases. Total ultrasound score was calculated, score >2 was seen in 62.3% of malignant cases and 18.4 % of benign cases [Table 1].

Table 1: Characteristics of Ovarian masses

Ovarian Mass	Benign	Malignant
Mean age in years	38.24±12.51	57.78±16.46
Mean CA125 serum level	27.3	547.2
Multilocular cysts	46.3%	76.2%
Solid Areas	22.3%	73.2%
% of Bilateral cases	13.1%	21.3%
Presence of Ascites	Absent	43.2%
Total ultrasound score of <2	81.2%	39.6%
Total ultrasound score of >2	18.4%	62.3%
RMI <200	90.2%	10.4%
RMI >200	8.2%	89.6%

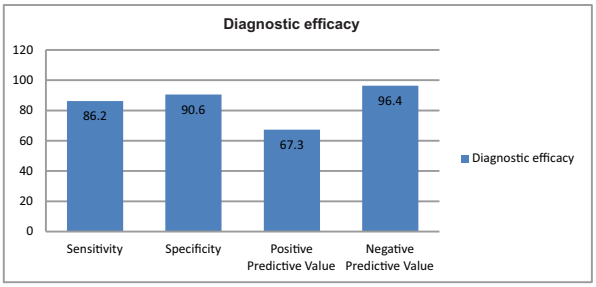

Fig. 1: Shows the diagnostic efficacy of RMI 2 scoring system.

DISCUSSION

In the 1990s, Jacobs et al. originally developed the RMI, which is known as RMI I.[10] Modifying RMI, Tingulstad et al. developed RMI II and III, with the alternation of the ratio of ultrasound score and postmenopausal status score.[11] Recently RMI IV was created by Yamamoto et al. by adding the parameter of the tumor size.[12] Over the past few years, the performance of RMI to distinguish benign from malignant adnexal masses has been well studied. However, how to discriminate borderline ovarian tumors from benign ovarian tumors has been difficulty over years, as BOTs present less typical tumor features.[13] In fact, the preoperative discrimination is quite important for BOTs, as the recommended surgery methods are different. Our study has revealed the effectiveness of using RMIs to predict tumor nature, which could help both surgeon and pathologist making pre and in operation decision for proper treatment to benefit patients, especially who wish to preserve their reproductive capacity before the operation. Pelvic masses are one of the most common reasons for the patient's referral to gynecologic oncology centres. The rate of malignancy in pelvic masses of premenopausal age group is approximately 24% and while in postmenopausal women it increases to more than 60%. Unfortunately most of these masses are asymptomatic or considered unimportant leading to delay in admission, difficulty in curative surgeries and ultimately decreased survival. 2/3rd of ovarian cancers are detected after metastasis or at stages 3 and 4 where the survival rate is very low. RMI is a straight forward algorithm that is simple to apply in clinical practice. It uses inexpensive tests that are commonly available and easily reproducible. It is the simple scoring system which can be used in daily clinical practice by all gynecologists in detecting malignant ovarian tumors. It is also reliable and convenient method for preoperative differentiation and early referral to gynecologist.[14]

Guidelines from the Royal College of Obstetricians and Gynecologists (RCOG) in the UK suggest using the RMI to categorise women with an ovarian mass into three groups. For tumours classified as low risk, the proposed management is expectant management or laparoscopic surgery by a generalist in a gynecology unit. If at moderate risk, laparoscopic surgery in a cancer unit by a surgeon with a special interest is suggested. If at high risk, referral of the woman to a cancer centre for a full staging procedure by a subspecialist gynecological oncologist is advised.[16] CA125 levels are taken as serum values applied directly as u/ml. Ultrasonography is widely accepted as best imaging method for evaluation of ovarian pathology. The sensitivity of ultrasound in present study is 63.2 % which is similar to Aziz etal.[17] Univariate analysis of the individual ultrasound parameters showed that presence of solid areas and ascites were highly suggestive of malignancy CA 125 level is widely accepted as a useful biomarker for estimating the risk of ovarian malignancy. The present study has demonstrated the usefulness of the RMI in pre-referral evaluation of patients with demonstrated pelvic masses. It confirmed the ability of RMI 2 to discriminate correctly between malignant and benign pelvic masses, and confirmed the high specificity of the RMI at the optimal cutoff point of 200. There was a significant difference between the two groups ($p < 0.01$). The index (RMI 1) developed by Jacobs et al,[15] for distinguishing benign and malignant masses preoperatively at a cut off level of 200 had a sensitivity of 86.2% and a specificity of 90.6%. Yorito Yamamoto et al6 found that the optimum identification of malignant pathology with RMI 2 with cut off 200 showed sensitivity of 86.2 % and specificity of 89.6%. A lower specificity would lead to an undue number of referrals of benign cases, which is unacceptable for the referring hospital and unmanageable for the special centres. On the other hand, this will aid in selection of cases for a conservative nonsurgical approach, for example, ultrasound guided aspiration of clear cysts or those which can be managed by a general gynecologist. The positive predictive value of RMI 2 was 69.5% which is almost similar to previous study by Watcharda et al[17]. The sensitivity of RMI is almost similar to other studies when compared to O beidat et al and Jacobs et al.[15]

CONCLUSION

These findings suggest that RMI is valuable, reliable and applicable method in the primary evaluation of patients with pelvic masses. Because of the simplicity of the method it can be used in daily clinical practice in non specialized gynaecologic departments and by all gynecologists for differentiating benign from malignant ovarian masses. Hence RMI is very useful in preoperative evaluation of ovarian mass even in rural population.

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