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DIAGNOSTIC ACCURACY OF THE RISK OF MALIGNANCY INDEX IN DISTINGUISHING BENIGN AND MALIGNANT ADNEXAL MASSES

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Abstract

Background: Adnexal masses, located in the ovaries, fallopian tubes, or nearby tissues, present a common challenge in gynecology. These masses can have diverse underlying causes, making their clinical significance complex to determine. To fully comprehend their impact, it is essential to consider the unique characteristics of these masses in different age groups.

Methods: A prospective observational study was conducted to assess the diagnostic accuracy of the Risk of Malignancy Index (RMI) in distinguishing benign from malignant adnexal masses. The study included 150 patients with confirmed adnexal masses of any age. Clinical and ultrasonographic evaluations, CA-125 measurements, and RMI calculations were performed. Histopathological results were used to confirm the nature of the masses.

Results: The study revealed a significant difference in RMI scores between benign and malignant cases ($p < 0.0001$). Patients with RMI scores ≤200 predominantly had benign masses (72.7%), while the majority of those with RMI scores >200 had malignant masses (14%). Significant associations were observed between CA-125 levels and histopathological reports ($p = 0.004$) and between ultrasound scores and histopathological reports ($p < 0.0001$). Age-specific patterns of adnexal masses were also noted.

Conclusion: The diagnostic accuracy of the Risk of Malignancy Index in distinguishing benign and malignant adnexal masses is pivotal in gynecological practice. This tool offers a comprehensive approach to risk assessment, which is essential for early detection and precise management of ovarian malignancies, ultimately improving patient outcomes.

Keywords: adnexal masses, Risk of Malignancy Index, ovarian cancer, diagnostic accuracy, CA-125, ultrasound, gynecology, age-specific patterns, histopathology

Introduction

Adnexal masses, found in the ovaries, fallopian tubes, or nearby tissues, present a common challenge in gynecology across all age groups. These masses can have diverse underlying causes, making their clinical significance complex to determine. To fully comprehend their impact, it is essential to consider the unique characteristics of these masses in different age groups.[1]

In girls under the age of 9, a striking 80% of ovarian masses are malignant, mainly germ cell tumors. During adolescence, mature cystic teratomas, or dermoid cysts, account for approximately 50% of adnexal neoplasms. Although endometriosis is

relatively rare in adolescent women, it may still be the cause of painful masses in up to 50% of cases.[2] In sexually active adolescents, the consideration of a tubo-ovarian abscess as the cause of an adnexal mass is essential. Among reproductive-age women, the majority of adnexal masses are benign, but around 10% are malignant, with a significant proportion having low malignant potential in patients under 30.[3]

Managing adnexal masses is a complex process influenced by factors such as the type of mass, urgency of presentation, and suspicion of malignancy. Ovarian cancer is one of the most common malignancies in females, and the lifetime risk for women in the United States undergoing surgery for suspected ovarian neoplasms is 5 to 10%. The peak incidence of invasive epithelial ovarian cancer is around age 60, with varying malignancy rates in premenopausal and postmenopausal women.[4]

Ovarian cancer is a significant surgical challenge, with the highest fatality-to-case ratio among gynecological cancers. Despite a low estimated lifetime risk, the mortality rate remains high. In India, ovarian cancer is the fourth most common cancer, earning the nickname "silent killer" due to its vague symptoms.[5] Early differentiation of ovarian masses into benign and malignant lesions is critical for effective management. Certain adnexal masses have characteristic sonographic features that render surgical exploration unnecessary. Benign tumors can often be managed with minimally invasive procedures. However, when there is a perceived high risk of ovarian cancer, referral to a specialized oncology center is the preferred approach.[6]

The survival rate for ovarian malignancies significantly depends on the stage at diagnosis. Early detection is crucial, and the Risk of Malignancy Index (RMI) has emerged as a promising tool to address this challenge. RMI considers menopausal status, ultrasound findings, and serum CA-125 concentrations, offering a comprehensive approach. RMI 1 has been recommended by NICE guidelines as a screening tool for high-risk women. RMI 2, developed in 1996, boasts impressive diagnostic accuracy, making it a valuable asset for differentiating benign and malignant tumors.[7]

Using an objective tool like RMI ensures that patients with likely malignant tumors are promptly referred to specialized oncology centers. Timely referral to a gynecological oncologist has been shown to improve survival rates. This study aims to assess the diagnostic accuracy of the Risk of Malignancy Index (RMI) in distinguishing between benign and malignant adnexal masses. Such an evaluation has the potential to enhance early detection and precise management of ovarian malignancies, ultimately improving the quality of care and patient outcomes in this challenging clinical field.[8]

Materials And Methods

Study Setting: This prospective observational study was conducted at the Department of Obstetrics and Gynaecology, Baba Saheb Ambedkar Medical College and Hospital.

Study Population: The study included patients residing in the catchment area of Dr. Baba Saheb Ambedkar Hospital, Rohini, Delhi.

Study Design: A prospective observational study was conducted.

Sample Size: A total of 150 patients with confirmed adnexal masses of any age were included.

Inclusion Criteria: All women with confirmed adnexal masses diagnosed either through clinical examination or ultrasonography.

Exclusion Criteria:

- Women with adnexal masses not requiring operative treatment (functional ovarian cyst).
- Patients with adnexal masses presenting as acute emergencies (e.g., ectopic pregnancy, torsion of any ovarian mass).

Methodology: This study obtained ethical and scientific clearance from the institute. Women diagnosed with adnexal masses through clinical and/or ultrasonographic examination were included after obtaining informed consent. A comprehensive history and physical examination were conducted to determine the nature and cause of the mass.

History:

1. Chief presenting complaints
2. Duration
3. Progression
4. General symptoms of malignancy (e.g., weight loss, loss of appetite, continuous malaise)

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5. Menstrual history
6. Obstetric history
7. Family history (ovarian cancer, breast cancer, GIT cancer, endometrial cancer)
8. Past medical surgical history
9. Personal history (sleep, appetite, bladder bowel habits, drug addiction, drug allergies)

Clinical Examination:

1. General physical examination
2. Systemic examination to rule out underlying systemic diseases
3. Gynecological examination to assess mass origin, size, shape, consistency, mobility, laterality, tenderness, and relation to surrounding structures.

Investigations: In addition to routine tests, CA-125 and ultrasound were performed. The Risk of Malignancy Index (RMI) was calculated based on history, ultrasound findings, and CA-125 values. RMI = ultrasound score x menopausal score x CA-125. The ultrasound score ranged from 1 to 4, based on the number of abnormal ultrasound features. Menopausal status was scored as 1 for premenopausal and 4 for postmenopausal women. CA-125 values in IU/ml were directly used in RMI calculation. An RMI cutoff of 200 was used to classify patients as high risk or low risk for ovarian malignancy.

Follow-up: All patients were followed up postoperatively, and their intraoperative findings and histopathology results were collected from their records. The histopathologic findings were analyzed and correlated with preoperative RMI values.

Results

Table 1. Distribution of patients according to age groups: In our study, 150 patients were categorized into three age groups. The majority of patients (52.7%) fell in the 31-40 age group, with 38% in the ≤30 group and 9.3% in the >40 group. The mean age of the patients was 33.1 years with a standard deviation of 6.74 years.

Table 2. Risk of Malignancy Index (RMI): We calculated the Risk of Malignancy Index (RMI) score for all patients. A significant difference was observed in RMI scores between benign and malignant cases ($p < 0.0001$). The majority of patients (78%) had RMI scores of ≤200, of which only 5.3% were malignant. In contrast, 22% of patients had RMI scores >200, and 14% of them were malignant.

Table 3. Distribution of patients according to CA-125 levels and HPE report: This table demonstrates the distribution of patients based on CA-125 levels and histopathological examination (HPE) reports. Patients with chocolate cysts had significantly lower CA-125 levels (4%) compared to other types. Conversely, serous cystadenocarcinoma patients had elevated CA-125 levels. A significant association was found between CA-125 levels and HPE reports ($p = 0.004$).

Table 4. Distribution of patients according to US score and HPE report: This table illustrates the distribution of patients based on ultrasound (US) scores and HPE reports. Patients with chocolate cysts predominantly had US scores of 1, while those with serous cystadenocarcinoma primarily had US scores of 4. A highly significant association was observed between US scores and HPE reports ($p < 0.0001$).

Table 1. Distribution of patients according to age groups.

Sr. No	Age group	Benign *n* (%)	Malignant *n* (%)	Total
1	**≤30**	57 (47.1 %)	0	57 (38 %)
2	**31-40**	61 (50.4 %)	18 (62 %)	79 (52.7 %)
3	**>40**	3 (2.5 %)	11 (38 %)	14 (9.3 %)

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	Total	**121 (80.7 %)**	**29 (19.3 %)**	**150 (100 %)**
Mean ± SD - 33.1 years ± 6.74				

Table 2. Risk of Malignancy Index (RMI)

RMI Score	Benign *n* (%)	Malignant *n* (%)	Total	p value
≤200	109 (72.7 %)	8 (5.3 %)	117 (78.0 %)	<0.0001
>200	12 (8 %)	21 (14 %)	33 (22.0 %)	
Total	**121 (80.7 %)**	**29 (19.3 %)**	**150 (100 %)**	

Table 3. Distribution of patients according to CA-125 levels and HPE report.

HPE report	CA-125 levels (IU/ml)			Total	p value
	<35	35-100	101-200		
Chocolate cyst	6 (4 %)	2 (1.3 %)	0	8 (5.3 %)	0.004
Complex cyst	1 (0.7 %)	0	0	1 (0.7 %)	
Corpus luteal cyst	10 (6.7 %)	15 (10 %)	0	25 (16.7 %)	
Dermoid cyst	5 (3.3 %)	7 (4.7 %)	0	12 (8.0 %)	
Follicular cyst	5 (3.3 %)	1 (0.7 %)	0	6 (4.0 %)	
Haemorrhagic cyst	6 (4 %)	0	0	6 (4.0 %)	
Serous cystadenoma	10 (6.7 %)	23 (15.3 %)	0	33 (22.0 %)	
Mucinous cystadenoma	15 (10 %)	15 (10 %)	0	30 (20.0 %)	
Borderline tumour	0	1 (0.7 %)	0	1 (0.7 %)	
Serous cystadenocarcinoma	3 (2 %)	10 (6.7 %)	6 (4 %)	19 (12.7 %)	
Mucinous cystadenocarcinoma	2 (1.3 %)	7 (4.7 %)	0	9 (6.0 %)	
Total	**63 (42 %)**	**81 (54 %)**	**6 (4 %)**	**150 (100 %)**	

Table 4. Distribution of patients according to US score and HPE report.

HPE report	US Score	Total	p value

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	US 1	US 4		
Chocolate cyst	8 (5.3 %)	0	8 (5.3 %)	
Complex cyst	1 (0.7 %)	0	1 (0.7 %)	
Corpus luteal cyst	23 (15.3 %)	2 (1.3 %)	25 (16.7 %)	
Dermoid cyst	10 (6.7 %)	2 (1.3 %)	12 (8.0 %)	
Follicular cyst	4 (2.7 %)	2 (1.3 %)	6 (4.0 %)	
Haemorrhagic cyst	6 (4 %)	0	6 (4.0 %)	<0.0001
Serous cystadenoma	15 (10 %)	18 (12 %)	33 (22.0 %)	
Mucinous cystadenoma	15 (10 %)	15 (10 %)	30 (20.0 %)	
Borderline tumour	1 (0.7 %)	0	1 (0.7 %)	
Serous cystadenocarcinoma	0	19 (12.7 %)	19 (12.7 %)	
Mucinous cystadenocarcinoma	1 (0.7 %)	8 (5.3 %)	9 (6.0 %)	
Total	**84 (56 %)**	**66 (44 %)**	**150 (100 %)**	

Discussion

Our Study investigated the diagnostic accuracy of the Risk of Malignancy Index (RMI) in distinguishing benign from malignant adnexal masses, a critical issue in gynecological practice. Our discussion will focus on key aspects of this study, including the patient distribution based on age, RMI scores, CA-125 levels, and ultrasound (US) scores, and their implications for clinical practice.[9]

Our study revealed a notable distribution of patients across age groups. Most patients with adnexal masses were in the 31-40 age group (52.7%), highlighting the significance of this age range in gynecological care. Understanding the age-specific characteristics of adnexal masses is crucial, as the causes and potential malignancy risks differ among age groups.[10] For instance, in adolescents, mature cystic teratomas and endometriosis are common causes, while in older patients, ovarian cancer becomes a more significant concern. Clinicians should be vigilant about these age-related patterns when assessing adnexal masses.[11]

The Risk of Malignancy Index (RMI) is an established tool that combines clinical parameters such as menopausal status, ultrasound findings, and CA-125 levels. This study showed that the RMI score is effective in distinguishing between benign and malignant adnexal masses. Patients with RMI scores ≤200 predominantly had benign masses (72.7%), while the majority of those with RMI scores >200 had malignant masses (14%). This significant difference ($p < 0.0001$) underscores the utility of the RMI in risk assessment. This tool can play a pivotal role in facilitating the early detection of ovarian malignancies.[12]

The study also investigated the association between CA-125 levels and histopathological examination (HPE) reports. Patients with chocolate cysts, generally benign, had lower CA-125 levels, while those with serous cystadenocarcinoma, malignant in nature, exhibited elevated CA-125 levels. This relationship ($p = 0.004$) supports the well-known use of CA-125 as a tumor marker for ovarian cancer. It emphasizes the importance of integrating CA-125 levels into the diagnostic process and considering the specific HPE results when interpreting these levels.[13]

Another significant finding was the strong association between US scores and HPE reports. Adnexal masses with certain characteristics, such as chocolate cysts, often had low US scores, while serous cystadenocarcinoma was associated with

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higher US scores. This correlation ($p < 0.0001$) highlights the diagnostic value of ultrasound in assessing adnexal masses. Clinicians can leverage this non-invasive imaging modality to make informed decisions about the need for surgical exploration, reducing unnecessary interventions in cases of benign masses.[14]

This study contributes valuable insights to the field of gynecology and oncology by underlining the importance of age-specific considerations, the utility of the RMI, and the significance of CA-125 and ultrasound findings in the accurate diagnosis of adnexal masses. Early detection and precise management of ovarian malignancies are critical to improving patient outcomes. This research emphasizes the potential of RMI in achieving these goals, providing a comprehensive approach to risk assessment. Timely referrals to specialized oncology centers and gynecological oncologists based on RMI scores can further enhance survival rates.[15]

Conclusion

This study emphasizes the critical role of the Risk of Malignancy Index (RMI) in distinguishing benign from malignant adnexal masses. The findings reveal the effectiveness of RMI in risk assessment, with significantly different outcomes observed between patients with RMI scores ≤200 and >200. Integrating clinical parameters, ultrasound, and CA-125 levels, the RMI offers a comprehensive approach to early detection and precise management of ovarian malignancies.

Understanding age-specific patterns of adnexal masses is crucial, as causes and potential malignancy risks vary across age groups. Moreover, the study highlights the importance of CA-125 levels and ultrasound in the diagnostic process. This research contributes valuable insights to gynecology and oncology, with the potential to improve patient outcomes by facilitating timely referrals and reducing unnecessary interventions.

While the study's single-center nature presents limitations, further multicenter trials and long-term follow-up of patients are warranted to validate these findings and enhance their clinical implications. In conclusion, the RMI is a pivotal tool for addressing the diagnostic challenges posed by adnexal masses in gynecological practice.

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