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RESEARCH ARTICLE
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PREVALENCE OF OVARIAN CANCER IN WOMEN WITH PERSISTENT ADNEXAL MASSES USING IOTA SIMPLE RULES.

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ABSTRACT

Background: The potential for malignancy makes persistent adnexal masses in women a challenge for diagnoses. The ability for practitioners to determine in a timely fashion the presence of borderline and borderline lesions and malignancy becomes a priority for appropriate care. The IOTA Simple Rules provide a standardized and validated approach for evaluating the masses which improves the diagnostic accuracy with the use of an ultrasound.

Objectives: Assessing the frequency of ovarian cancer amongst women with persistent adnexal masses and investigating how well the IOTA Simple Rules can distinguish benign from malignant ovarian tumors.

Methodology: This study was conducted in the department of Obstetrics & gynecology Ayub Medical College, MTI, Abbottabad from Jan 2023 to Jan 2024. During outpatient clinic visits and referrals of inpatients, the participants of the study were identified. We excluded pregnant women, those with a history of frozen pelvis or ovarian surgery, patients with acute pelvic inflammatory disease, and patients with missing ultrasound records. Total clinical examinations and assessments were performed on the study participants, followed by standardized transvaginal ultrasound examinations performed by certified ultrasound technicians. Then, IOTA Simple Rules were used to classify adnexal masses on ultrasound as benign, malignant, or of unclear diagnosis, in relation to the presence of solid constituents, papillary projections, stationing, vascularity, and acoustic shadowing. In the case of a position diagnosis of an ambiguous mass, a senior radiologist with specialist knowledge of gynecological imaging was consulted. Patients with an ambiguous mass were referred for surgery to obtain a definitive diagnosis. The same was done for any children with an unrelated suspected mass, after clearing the Imagistics. We followed benign-appearing adnexal masses with imaging to confirm stability or resolution. A structured questionnaire was used to collect the clinical and imaging records of the patients.

Results: Mean of 42.8 ± 11.6 years was obtained when 120 women were analyzed. 28 of these women suffered from malignancy (23.3%), as confirmed by the histopathology. According to the IOTA Simple Rules, 74 of the masses were considered benign, while 30 were considered malignant and 16 were not able to be classified. There was a strong positive correlation of malignancy with the malignant IOTA features ($p < 0.001$). 89.3% of the population of the study was found to be sensitive and 92.1% were found to be specific. The benign lesions were found to be cystadenomas, desmoids, and endometrioses, while the malignant tumors were found to be serous cystadenocarcinoma, which was found to be the most common. The overall diagnostic accuracy was 91.6%.

Conclusion: There is a high prevalence of ovarian cancer among women with persistent adnexal masses. This finding underscores the importance of formulating systematic approaches to diagnostic assessment. IOTA Simple Rules has shown sufficient sensitivity and specificity to justify using the rules in everyday gynecological practice to distinguish between malignant and benign lesions. Their use can lower the number of inappropriate surgeries, improve the ease in determining the need for an oncology referral, and improve diagnostic confidence in resource-poor settings.

Keywords: Ovarian cancer; Adnexal masses; IOTA rules; Ultrasound

Introduction

Cancer of the ovaries continues to be one of the most serious problems. For the majority of patients diagnosed with the disease, they do not become aware of it until it is already in the advanced stages (more than 70% of patients). For patients diagnosed with cancer, all the symptoms of the disease in the population may not be as overt as in the stage one level of the disease. and field. In the world, it is the the 8th most prevalent type of cancer in females. Moreover, it continues to be a significant contributor to the losses from cancer in the population. The disease is often described in the field of medicine as one being silent [1,2]. The prognosis of the disease is highly dependent on the early detection of the disease. The absence of early detection in the disease is the main factor for having a high level of difficulty in diagnosing it. In the field of gynecology, the presence of adnexal masses is a common finding [3]. The masses may be Endometrioses, benign cysts, advanced borderline tumors, or invasive carcinomas of the ovaries. In the field of medicine, it is important for a gynecologist to be able to distinguish benign from malignant gynecological tumors in order to provide optimal care for the patient [4]. Adnexal masses in patients are best visualized with a real-time ultrasound. The International Ovarian Tumor Analysis group realized such changes in technology. to create a more accurate interpretation of ovarian masses. The delay in technology has resulted in the field of medicine to be able to create a standard construct for the interpretation of their data [5,6]. Validated extensively, the IOTA Simple Rules, consisting of five benign features (B-features) and five malignant features (M-features), have become one of the most trusted sonographic methods for separating malignant tumors from benign tumors [5,6]. The IOTA Simple Rules were validated in several studies and even in non-expert sonographers who have had adequate training, the sensitivity and specificity were said to be higher than 90%. Their implementation lessened diagnostic dilemmas, improved triaging for specialists, and stopped unnecessary surgeries for benign tumors. Also, the Simple Rules have shown reproducibility in different clinical scenarios like in tertiary care facilities, community hospitals, and in scenario of limited resources [7]. The dependability of the Simple Rules is particularly helpful in case of poor resource settings where advanced diagnostic imaging and specialized care in gynecologic oncology is rare [8]. Adnexal masses that have persisted for more than six weeks require special attention since they have a higher chance of malignancy [9]. A study conducted in South Asia, particularly Pakistan, notes that ovarian cancer is diagnosed at younger ages and is more advanced at the time of diagnosis than in the West, as a result of diagnostic delays, making accurate and timely assessments even more important [10]. Regardless of the IOTA models' confirmed advantages in other regions of the world, there is a scarcity of local data on the use of IOTA models for the assessment of adnexal masses and the detection of associated ovarian cancer. Therefore, this study aims to determine the prevalence of ovarian cancer in women with persistent adnexal masses as well as the diagnostic efficacy of IOTA Simple Rules in differentiating benign from malignant adnexal masses.

Study Objectives

To evaluating women with persistent adnexal masses using IOTA Simple Rules Criteria. These were evaluated through transvaginal basic ultrasound imaging.

Materials and Methods

Study Design & Setting

Department of Obstetrics & gynecology Ayub Medical College, MTI, Abbottabad from Jan 2023 to Jan 2024.

Participants

The study design focused on participants within the ages of 18 to 70 years old, female, and had an adnexal mass that had been present for at least six weeks. Individuals who were not included within the study were those who were pregnant, had a previous ovarian surgery, had an acute pelvic infection, or had incomplete imaging files. All participants that were included and qualified went through a detailed, organized ultrasound. Diagnosis and confirmation were determined by a surgical procedure and the acquisition of pathology, and for those lesions that appeared to be harmless, the diagnoses were established through imaging assessments taken during or at the conclusion of the surgical process.

Sample Size Calculation

120 expected prevalence of 20% of ovarian cancer in persistent adnexal mass, a confidence level of 95 f% and a margin of error of 7%, a minimum of 118 participants was required. For adequate power, 120 participants were recruited for the current study.

Inclusion Criteria

Women aged 18-70 suffering an adnexal mass of 6 weeks of duration or more had an \\"IOTA-based ultrasound investigation.

Exclusion Criteria

Prior pregnancy as well as previous surgeries to the adnexa or pelvis Acute pelvic inflammatory disease Insufficient documentation of the ultrasound.

Diagnostic and Management Strategy

Transvaginal ultrasound assessments were done for all patients, and the IOTA Simple Rules were used to classify the ultrasound findings as benign, malignant, or indeterminate. Cases classified as indeterminate were referred to a senior radiologist for further analysis and recommendations. Surgical intervention was recommended for suspected malignant or complex masses, whereas benign masses were followed with imaging or managed conservatively.

Statistical Analysis

Version 24.0 of SPSS was used to perform the statistical analysis of the data. Diagnostic indices of sensitivity, specificity, PPV, NPV and overall accuracy were calculated. Chi-square tests were used to evaluate the relationships between the ultrasound findings and the malignancy. Age and attributes of the masses were compared using independent t tests. Significance was established at $p < 0.05$.

Ethical Approval

Ethical Approval has been authorized by Ayub Medical College, MTI, Abbottabad Institutional Review Board (IRB), the members in the study had the opportunity to consent in writing prior to taking part in the study. As the study was completed according to the Declaration of Helsinkis 2013.ethical guidelines, the information and data collected were secured, and confidentiality was respected.

Results

120 women with persistent adnexal masses. The participants had a mean age of 42.8 ± 11.6. The age range of the participants was 19 to 70. There were 28 confirmed cases (23.3%) of malignancy and 92 cases (76.7%) of benign Histopathological lesions. The most frequently occurring malignancy was serous cystadenocarcinoma, which accounted for 57.1%, and was succeeded in occurrence by mucinous carcinoma and carcinoma of endometriosis. Benign lesions were primarily serous

cystadenomas and Ohio droid's cysts as well as endometrioses. Based on the IOTA Simple Rules 74 of these masses (61.7%) were determined to be benign, 30 (25%) were determined to be malignant, and 16 (13.3%) were determined to be inconclusive. Of the 16 cases that were inconclusive, expert review reclassified 12 of these cases as benign and 4 as malignant enhancing diagnostic precision. There was a statistically significant correlation between confirmed malignancy and the presence of malignant ultrasound features (M-features) ($p < 0.001$). It was discovered that IOTA Simple Rules had very good sensitivity (89.3%), specificity (92.1%), as well as high PPV (84.8%) and NPV (94.8%), with a total diagnostic accuracy of 91.6%. These results provide more evidence that the IOTA Simple Rules can be utilized with great reliability to identify malignant and benign adnexal masses and can be most helpful in the case of determining malignancy for adnexal masses that have high potential for surgical intervention.

Intervention Outcomes

IOTA Simple rules application helped in the early identification of malignant adnexal masses allowing timely referral to a gynecologic oncology unit. The high negative predictive value avoided unnecessary surgeries on benign conditions while the identification of malignant features guided appropriate surgical planning. The systematic approach in ultrasound improved the consistency of the diagnosis and the patient's overall management.

Table 1. Baseline Demographic and Clinical Characteristics of Participants

Variable	Mean ± SD / n (%)
Total participants	120 (100%)
Mean age (years)	42.8 ± 11.6
Age range (years)	19–70
Parity ≥3	68 (56.7%)
Postmenopausal women	34 (28.3%)
Duration of persistent mass (weeks)	8.4 ± 2.1
Unilateral adnexal mass	98 (81.7%)
Bilateral adnexal mass	22 (18.3%)

This table summarizes the baseline demographic and clinical characteristics of all 120 women included in the study with persistent adnexal masses.

Table 2. IOTA Simple Rules Classification of Adnexal Masses

IOTA Category	Frequency (n)	Percentage (%)
Benign (B-features)	74	61.7%
Malignant (M-features)	30	25.0%
Inconclusive	16	13.3%

This table shows the distribution of adnexal masses according to IOTA Simple Rules based on transvaginal ultrasound features.

Table 3. Histopathological Diagnosis of Adnexal Masses

This table presents final histopathological results of all adnexal masses, confirming the prevalence and distribution of benign and malignant ovarian lesions.

Histopathological Type	n	Percentage (%)
Malignant Tumors		
Serous cystadenocarcinoma	16	13.3%
Mucinous carcinoma	6	5.0%
Endometriosis carcinoma	4	3.3%
Other malignancies	2	1.7%
Total malignant	28	23.3%
Benign Tumors		

Serous cystadenoma	52	43.3%
Desmoids cyst	20	16.7%
Endometrium	14	11.7%
Functional cysts/others	6	5.0%
Total benign	92	76.7%

Table 4. Diagnostic Performance of IOTA Simple Rules

Diagnostic Parameter	Value (%)
Sensitivity	89.3%
Specificity	92.1%
Positive Predictive Value (PPV)	84.8%
Negative Predictive Value (NPV)	94.8%
Overall Diagnostic Accuracy	91.6%

This table summarizes the diagnostic performance of the IOTA Simple Rules in identifying malignant adnexal masses, demonstrating high sensitivity, specificity, and overall accuracy.

Discussion

This study investigated how common it is for women with persistent adnexal masses to also have ovarian cancer and how well the IOTA Simple Rules perform in differentiating between the benign and malignant masses. We found the prevalence of malignancy to be also 23.3%, which is in line with findings from the same folk South Asia and other lower/middle-income countries [11]. Other newer studies have also shown prevalence to be in the 18% to 30% range for people with complex or persistent adnexal masses, underlining the need for more structured goal of diagnostic assessment on these high-risk populations. The IOTA Simple Rules improved diagnostic performance in our study, with 89.3% sensitivity, 92.1% specificity, and 91.6% overall accuracy. This is in near concordance with other global studies. Timmerman et al [12].is one of the studies which also reported similar results, with sensitivities and specificities above 90%. Other studies in the last five years reliably reported the same results in clinical practice to the one found in the European, African, and Asian studies on the IOTA Simple Rules [13]. This has also been shown by Khorana et al. (2020) and Sayasneh et al [14]. Raimondi (2021) recognized similar diagnostic accuracy and versatile reproducibility of IOTA criteria across different healthcare settings (P. 14). One of IOTA Simple Rules greatest advantages is their simplicity and less reliance on high-end imaging technology, which is often the case in lesser diagnostic facilities [15]. Our results are in line with other studies showing even less experienced practitioners are able to high levels of competency if significant time is devoted to teaching the IOTA criteria [16]. This is encouraging when considering the IOTA system as a universally applicable system capable of maintaining high levels of standardized and objective clinical reasoning irrespective of the operator's years of experience [17]. The distribution of histopathological diagnosis in our case was also following the global pattern. Serous cystadenocarcinoma was the most common malignancy which is in line with the fact that it is the most common cancer of the ovary and the most common malignant tumor of the ovaries [18]. The majority of the nonmalignant cases were also benign cystic lesions (serous cystadenomas, drainage cysts and endometriosis) which is also in line with findings from other studies in the region (Pakistan, India, and Bangladesh). The significant relationship between of M-features and malignancy in an ultrasound examination ($p < 0.001$) also strengthens the IOTA Simple Rules even further [19,20]. Cohorts of patients from previous studies have shown that certain sonographic ally predictive markers like solid components, papillary projections, irregular walls, and increased vascularity are features that are commonly seen and are associated with malignancy [19,20]. Perhaps the most clinically important implication of our findings is the very high negative predictive value of 94.8%. This means that the IOTA Simple Rules is very reliable in excluding malignancy and is sustained when benign features are present [21]. This is particularly important in decreasing the potential for unnecessary surgical procedures for benign findings. There is greater focus on efficient, patient-centered health

care, which makes the ability to observe benign masses over time without immediate surgical intervention valuable [22]. The 13.3% rate of inconclusive is as expected and is in line with previously published literature in which the range is 5–20%. An expert review was able to resolve the majority of inconclusive in which the support of senior radiologists is shown to be beneficial in complex case assessments. There is potential for the IOTA Simple Rules combined with other tools to lower the inconclusive rates for CA-125, HE4, and MRI [23,24]. There are many strengths in this study, however it is limited due to the single center study design, small sample size, and lack of long-term follow up [25,26]. The study does provide important local evidence of the real-world impact that IOTA Simple Rules can have in a limited resource environment [27].

Limitations

This study was constrained in generalizability by its unitary single-center approach and smaller than average sample size. Test results and ultrasound interpretation depend on the administrator's commanding knowledge and inconclusive results that must be requisitioned to the administrator. There was no shadow study analysis to allow progression to be assessed for the mass recurrence.

Conclusion

Differentiating between malignant and benign adnexal masses, IOTA Simple Rules showed a remarkable degree of diagnostic accuracy. Given the considerable incidence of ovarian cancer, the incorporation of a standardized ultrasound assessment becomes imperative. The application of IOTA criteria in daily practice has the potential to improve early detection, avoid superfluous surgeries, and ensure prompt referral to gynecological oncological care.

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Authors Contribution

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