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CHARACTERIZATION OF DIFFERENT OVARIAN MASSES USING IOTA ULTRASOUND RULES: A CROSS-SECTIONAL STUDY.

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Abstract

Background

An adnexal lump in a woman is a common clinical condition. Accurately defining ovarian cancers is essential because it facilitates the identification of benign ovarian masses, which can then be treated conservatively to lower morbidity.

Aim

The purpose of the investigation was to determine the diagnostic value of IOTA ultrasonography rules, as well as to assess and evaluate the guidelines' sensitivity and specificity about histological diagnosis and their suitability for use as a tool at our tertiary care center for the early detection of ovarian cancer.

Methods

A cross-sectional investigation was carried out including women who had been recruited with at least one adnexal mass. When two adnexal masses were present, the analysis took into account the mass with the more intricate ultrasonography morphology. The masses were characterized by evaluating the sonographic morphology of the masses and doing a color Doppler examination. A link between sonography and histopathology was found using suitable statistical techniques.

Results

Using these guidelines, 50 individuals underwent USG; of these, 31 had benign, 15 had cancer, and 4 had unclear results. 30 of the 31 masses on the final HPE report that the simple rules had predicted to be benign turned out to be benign based on histology. Histology revealed that 14 of the 15 masses that the basic rules predicted to be cancer were malignant.

Conclusion

The study evaluates the effectiveness of simple rules in distinguishing between benign and malignant adnexal masses. Despite yielding inconclusive results in about 6.4% of cases, the diagnostic performance improves with extensive training provided to resident doctors.

Recommendations

It is recommended to integrate the IOTA ultrasonography rules into tertiary care gynecological diagnostic protocols. Comprehensive training for resident doctors is crucial to enhance diagnostic accuracy and minimize inconclusive results.

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Introduction

For women, adnexal masses are a prevalent clinical issue. Accurately describing these ovarian tumors is essential because it facilitates the identification of benign ovarian masses. Conservative care may be used in these benign masses, which would lower morbidity. Cysts and tumors classified as ovarian masses are the most common type of pelvic masses. The mass's size, movement, consistency, shape, potential internal watery component, and accompanying pain are all important characteristics to consider when diagnosing the type of mass [1]. The distinction between benign and malignant adnexal masses has been made using a variety of investigative techniques, including the morphological scoring system and logistic regression analysis [2]. The best test now available for classifying patients with ovarian tumors is the risk of

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malignancy index or RMI. Simple ultrasonography guidelines for the diagnosis of ovarian cancer were proposed by the IOTA group in 2008. These guidelines are predicated on the presentation of specific sonographic findings, some of which are suggestive of malignancy (M features) and others of which are indicative of benignity (B features).

Malignant tumor prediction rules (M rules)

M1 non-normal solid tumor

M2 Ascites is present M3 At least four structures called papillary

The maximum diameter of the M4 irregular multilocular solid tumor is less than 10 cm.

M5 Very strong blood flow (color score 4)

Rules for predicting a benign tumor (B rules)

B1 Unilocular

B2 Presence of solid components with the largest diameter < 7 mm

B3 Presence of acoustic shadows

B4 Smooth multilocular tumor with the largest diameter < 10 cm

B5 No blood flow (color score 1)

A variety of diagnostic techniques are available to determine if ovarian tumors are benign or malignant. These consist of Doppler sonography, sonographic morphology, clinical evaluation, and CA125 [3-4]. Initially, using ultrasound to assess ovarian cancers was a complicated process that required a high level of knowledge. However, in 2008, the IOTA published simple guidelines, and multiple clinical investigations later proved the utility of these guidelines. To clarify and establish their use as a tool in the early identification of ovarian cancer, we used these straightforward guidelines for patients who were admitted to our tertiary care facility.

The investigation aimed to determine the diagnostic value of IOTA ultrasonography rules, as well as to assess and evaluate the guidelines' sensitivity and specificity about histological diagnosis and their suitability for use as a tool at our tertiary care center for the early detection of ovarian cancer.

Materials and Methods

Study design

The present research was a prospective cross-sectional investigation.

Study setting

The study was carried out in Indira Gandhi Institute of Medical Sciences, Patna, Bihar, India. It was done between August 2022 to January 2023.

Participants

In the study, women who had at least one adnexal mass were enrolled.

Inclusion and exclusion criteria

We included in our analysis the mass with the most complicated ultrasonography morphology when there were bilateral adnexal masses. Pregnancy, refusing transvaginal ultrasonography, and delaying surgery for more than 120 days after the ultrasound scan were the exclusion criteria. For every patient, transvaginal ultrasonography was done.

Sample size determination:

Patients who enrolled after filling the inclusion criteria. For calculating sample size the following formula was used:

$$N\Delta = \frac{2(Za+Z1-\beta)2\sigma 2}{2}$$

Where, N= sample size, Z is a constant

Za is set by convention according to the accepted error of 5% as 1.649 Z1-β is set by convention according to accepted 1-β or power of study of 80% as 0.8416Σ is the standard deviation estimated Δ is difference in the effect between two interventions (estimated effect size).

Procedure

If a big tumor could not be completely examined vaginally, trans-abdominal ultrasonography was done. Throughout the test, the masses were characterized by doing a color Doppler study and assessing the masses' sonographic morphology. If there were one or more M features but no B features, the mass was considered malignant. When neither B nor M rules were applied, or when none were present, the mass was deemed inconclusive. The link between sonography and histopathology was then carried out.

Bias

There was a chance that bias would arise when the study first started, but it was avoided by giving all participants identical information and hiding the group allocation from the nurses who collected the data.

Statistical analysis

To determine the value of IOTA basic principles for comparing sonological and histological reports of the ovarian masses, data was evaluated using kappa metrics.

Ethical considerations

The ethics committee gave its approval to the protocol, and each woman provided informed permission.

Results

In the study, 56 participants were recruited based on having at least one adnexal mass. However, 6 participants were excluded, including pregnant women, those refusing transvaginal ultrasonography, and individuals delaying surgery for more than 120 days after the ultrasound scan. These exclusions were made to ensure the study's focus on evaluating the diagnostic value of IOTA ultrasonography

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rules for adnexal masses without potential confounding factors

Table 1: Demographic characteristics

Demographic Characteristics	Participants
Age (years)	Mean: 40.5, Range: 15-72
Menopausal Status (Postmenopausal)	33%
Parity (Nulliparous)	27%

Our study had 50 patients in total. 33% of the patients were postmenopausal, and the mean age was 40.5 (range: 15–72 years). Of the patients, 27% were nulliparous. Using the IOTA guidelines, the USG found that 31 tumors were benign, 15 were malignant, and 4 were inconclusive. 30 of the 31 masses on the final HPE report that the basic rules predicted to be benign turned out to be benign based on histology. Histology revealed that 14 of the 15 masses that the basic rules predicted to be cancer were malignant. The results of the sonogram and the histopathological reports appeared to be in good accord (Table 3).

Table 2: Clinical characteristics

Clinical characteristics	Participants
Adnexal masses	50
Adnexal mass type	
- Benign	55.4%
- Malignant	26.8%
- Inconclusive	7.1%
- Not specified	10.7%
Histopathological confirmation	
- Available	82.1%
- Not available 17.9%	
Surgical intervention	
- Performed	92.9%
- Not performed	7.1%

Table 3: Concordance between Sonographic and Histopathological Findings

Nature or mass as per IOTA rules	Number	HISTOPATHOLOGICAL	
		BENIGN	MALIGNANT
MALIGNANT	15	2	12
INCONCLUSIVE	4	2	1
BENIGN	31	32	1

When removing the inconclusive cases, the IOTA basic guidelines appeared to be 91.3% sensitivity and 94% particular in distinguishing between benign and malignant tumors. Tables 2 and 3 illustrate the diagnostic accuracy of the system.

Table 2: IOTA basic principles' diagnostic accuracy while using histology as the gold standard (except in situations with conflicting results)

Parameters	Value	95% Cl
Accuracy	93.3	85.0-97.0
PPV	87.5	69.0-95.7
NPV	95.8	86.3-98.9
Specificity	94.0	83.8-97.8
Sensitivity	91.3	73.1-97.5

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Table 3: IOTA's basic principles for diagnostic accuracy include histology as the gold standard (classifying cases that are not conclusive as malignant)

Parameters	Value	95% Cl
Accuracy	93.3	81.1-94.7
PPV	87.5	61.6-90.2
NPV	96.0	86.3-98.9
Specificity	88.8	77.5-94.6
Sensitivity	92.0	75.0-97.7

Discussion

In our study, which comprised 50 patients, 31 (62.8%) of the mass suggestions were deemed to be benign, 15 (30.7%) to be malignant, and 3 (6.4%) to be inconclusive based on the basic IOTA guidelines. This was almost identical to Sharma B. et al.'s study [5], in which 26.2% of the tumors were classified as malignant and 67.2% as benign based on USG IOTA guidelines.

In their research, Timmerman D. et al. [6] discovered that the IOTA basic guidelines had a sensitivity and specificity of 91% and 96%, respectively, for removing indeterminate masses and 94% and 80% for classifying them as malignant. The results of a study by Fathallah K et al. [7] showed that, respectively, the sensitivity was 73% and 79%, the specificity was 97% and 88%, and the results were obtained both with and without the evaluation of inconclusive as malignant.

The results obtained by Nunes N et al. [8] were 97% sensitivity and 70% specificity when interpreting inconsistent masses as malignant masses, and 96% sensitivity and 89% specificity when omitting the inconclusive masses. IOTA guidelines are quite helpful in distinguishing between benign and malignant tumors as a result of all these observations.

These research findings were consistent with ours. It demonstrated 91.3% sensitivity and 94% specificity in ignoring the inconclusive masses and 92% sensitivity and 88.7% specificity in classifying the inconclusive masses as malignant.

In a related study, Sharma B et al. [5] found that IOTA basic rules had a 92.8% sensitivity, 93% specificity, 81.2% positive predictive value, a relatively high negative predictive value of 97.5%, and 92.9% accuracy for the identification of malignancy. After removing the inconclusive masses, our analysis revealed an accuracy of 93.2%, a positive predictive value of 87.5%, and a negative predictive value of 95.9%. With inconclusive masses classified as malignant, the accuracy was found to be 89.7%, the PPV was 79.3%, and the NPV was 95.9%.

The diagnostic performance of IOTA simple rules in distinguishing between benign and malignant ovarian cancers was assessed by Tantipalakorn C et al. [9], who discovered a sensitivity of 82.9% and a specificity of 95.3%. They concluded that even in the hands of less experienced examiners, the implementation of the IOTA basic criteria produced results that were satisfactory in terms of specificity.

The Royal College of Obstetricians has included these IOTA basic standards in their guidelines for assessing adnexal masses in women who are not yet menopausal [10]. The majority of women who receive an adnexal mass diagnosis are initially assessed by non-specialist examiners. These are basic and straightforward guidelines to understand. When non-expert examiners follow these guidelines, they yield reasonably satisfactory findings.

Our research showed that straightforward guidelines can distinguish between benign and malignant adnexal tumors. It has been demonstrated that the most effective technique for identifying benign or malignant adnexal tumors is pattern recognition. Our findings demonstrate that these guidelines can be rather reliably followed by observers with varying degrees of expertise. According to this study, the primary benefit of simple rules is that they are easy to use and don't require complex computer software. When estimating the likelihood of malignancy in an adnexal mass, skilled ultrasound examiners use both clinical and ultrasonic data. They also inadvertently employ a set of guidelines derived from their past findings when assessing a tumor.

Conclusion

In the study population, the occurrence of malignancy is correlated with the usefulness of basic rules. This method's drawback is that 6.4% of the results were equivocal and required additional pattern recognition analysis. The resident physicians' considerable training before starting the trial may be the cause of their improved diagnostic performance in this investigation. We believe that the IOTA basic guidelines provide a straightforward, user-friendly method for determining whether an adnexal mass is benign or malignant.

Limitations

The limitations of this study include a small sample population who were included in this study. Furthermore, the lack of a comparison group also poses a limitation for this study's findings.

Recommendation

Based on the findings of this study, it is recommended that the IOTA ultrasonography rules be integrated into the diagnostic protocols of gynecological departments in tertiary care centers. The simplicity and efficacy demonstrated by these rules in distinguishing between benign and malignant adnexal masses make them a valuable tool for the early detection of ovarian cancer. Moreover, the study highlights the importance of providing comprehensive training to resident doctors to enhance diagnostic accuracy and reduce inconclusive results. Implementing these guidelines can significantly improve patient outcomes by facilitating appropriate management strategies and reducing unnecessary interventions.

Acknowledgment

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List of abbreviations

IOTA - International Ovarian Tumor Analysis
USG - Ultrasonography
HPE - Histopathological Examination
CI - Confidence Interval
Cl - Confidence Level
PPV - Positive Predictive Value
NPV - Negative Predictive Value
RMI - Risk of Malignancy Index

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No funding was received.

Conflict of interest

The authors have no competing interests to declare.

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