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To Study The Effectiveness of International Ovarian Tumour Analysis (IOTA) Simple Ultrasound Rules in Determining Malignancy in Ovarian Tumours

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HIGHLIGHTS

1. IOTA rules assess ovarian Tumors.
2. Simple ultrasound identifies malignancy effectively.
3. Study analyzes diagnostic accuracy results.
4. Early detection improves patient outcomes.
5. Findings enhance clinical decision-making processes.

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ABSTRACT

The study investigates the effectiveness of the International Ovarian Tumor Analysis (IOTA) simple ultrasound rules in distinguishing between benign and malignant ovarian masses. Conducted as a prospective observational study at Army Hospital in New Delhi between August 2020 and July 2022, it involved 50 patients. The primary objective was to evaluate the accuracy of the IOTA rules in preoperative tumor characterization by comparing ultrasound findings with histopathology results. Throughout the study data on various tumor markers, such as CA-125, CEA, CA 19-9, and LDH were collected. Of these CA-125 stood out with a significant difference between benign and malignant groups, underlining its diagnostic importance. The IOTA rules demonstrated a sensitivity of 55.6% and a specificity of 97.6%, leading to an overall diagnostic accuracy of 90% in identifying ovarian malignancies. The high specificity indicates the rule's strength in accurately identifying benign masses, though the moderate sensitivity suggests limitations in detecting malignant cases. This highlights the importance of combining IOTA ultrasound results with tumor marker assessments for improved diagnostic accuracy. The findings emphasize that while the IOTA rules are highly valuable due to their specificity a comprehensive approach that integrates imaging and clinical data is essential for accurate ovarian cancer diagnosis. The study suggests that although the IOTA rules are a promising tool for differentiating ovarian masses further research is necessary to refine these rules and enhance early detection methods for ovarian cancer. This research supports the potential of IOTA rules as a standard diagnostic tool but underscores the need for ongoing improvements to better address the complexities of ovarian cancer detection.

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INTRODUCTION

Cancer is one of the leading causes of death worldwide and poses a significant challenge to life expectancy in many countries. Among gynecological cancers, ovarian cancer ranks third after cervical and uterine cancers, yet it has the worst prognosis and highest mortality rate. Although less common than breast cancer, ovarian cancer is significantly more deadly, being three times more lethal. Predictions indicate that by 2040, the mortality rate for ovarian cancer will increase considerably. Its high fatality rate is attributed to its asymptomatic nature, the secretive growth of tumors, and delayed symptom onset, which often leads to late stage diagnosis. This has earned ovarian cancer the nickname "silent killer" due to its stealthy progression and lack of early detection tools [1,2,3].

Ovarian cancer is particularly prevalent in Indian women, ranking as the third most common cancer among them and the eighth most common cancer overall, as per the Globocan 2018 report. In India, ovarian cancer accounted for 3.44% of all cancer cases and was responsible for 3.34% of cancer-related deaths in 2018. The survival rates for ovarian cancer vary dramatically based on the stage at which it is diagnosed. When detected early at Stage I, the 5-year survival rate is as high as 94%. Unfortunately, only 15% of cases are diagnosed at this stage, with the majority being identified at advanced stages (Stages III and IV), where the 5-year survival rate plummets to just 28%. This bleak prognosis for advanced-stage ovarian cancer underscores the urgent need for improved detection and treatment strategies [4,5].

In terms of tumor characteristics, more than 90% of benign ovarian tumors are found in premenopausal women undergoing surgery, while only 60% of tumors in postmenopausal women are benign. Early differentiation between malignant and benign ovarian tumors is critical to determining the appropriate course of action, such as monitoring, treatment, or surgery. Laboratory tests, including tumor biomarkers, play a vital role in this differentiation. The Carbohydrate Antigen 125 (CA125) was one of the first tumor markers identified for ovarian cancer. Although CA125 levels may be elevated in ovarian cancer patients, this biomarker has limited sensitivity in detecting early stage cancer and may also be elevated in non-cancerous conditions like menstruation, pregnancy, and endometriosis. In an effort to enhance diagnostic accuracy, other biomarkers, such as Human Epididymis Protein 4 (HE4), have been developed which is often overexpressed in ovarian cancer. However, while these biomarkers have reliable specificity, their sensitivity remains a challenge, prompting the development of algorithms like the Risk of Malignancy Index (RMI) and the Risk of Ovarian Malignancy Algorithm (ROMA) to improve diagnostic accuracy [6,7,8].

Despite these advancements, the majority of ovarian cancer cases are still diagnosed at an advanced stage, resulting in poor survival outcomes. The limited predictive value of current screening tools has done little to reduce the disease's mortality rate. Standard early detection methods, such as gynecological examinations, transvaginal ultrasounds, and CA125 testing, have not significantly improved outcomes for ovarian cancer patients. Treatment typically involves surgery and platinum-based chemotherapy, though in recent years, anti-angiogenic agents and poly(ADP-ribose) polymerase (PARP) inhibitors have also been incorporated into treatment regimens. However recurrence after initial treatment is common, and patients with relapsed ovarian cancer face lower chances of recovery due to higher rates of treatment failure. As a result, there is a growing demand for novel treatment approaches based on a deeper understanding of the molecular mechanisms underlying the disease [9,10,11].

To improve the evaluation and classification of ovarian tumors, the International Ovarian Tumor Analysis (IOTA) group was established in 1999. This group developed a set of standardized terms and guidelines for describing ovarian masses, known as the "10 Simple Rules." These rules are based on five ultrasound features associated with benign tumors and five features linked to malignant tumors. Depending on the presence of these features, ovarian masses can be classified as benign, malignant, or inconclusive. For instance, benign features include unilocular cysts and the presence of acoustic shadows, while malignant features include irregular solid tumors and the presence of ascites. The IOTA group's guidelines have proven to be highly effective in predicting the likelihood of malignancy in ovarian masses, with studies showing accurate predictions in 77% to 94% of cases. For masses classified as benign, the malignancy rate was less than 9%, while those classified as malignant had malignancy rates ranging from 69% to 94% [12,13,14].

While progress has been made in understanding and diagnosing ovarian cancer, significant challenges remain in early detection and treatment. The development of standardized diagnostic tools, like the IOTA group's 10 Simple Rules, represents a promising step forward. However, continued research into novel

biomarkers and treatment strategies is essential to improving survival rates and reducing the high mortality associated with this devastating disease [15].

The aim of this study is to assess the effectiveness of the International Ovarian Tumor Analysis (IOTA) simple rules in the preoperative characterization of ovarian masses. Additionally, the study seeks to evaluate the accuracy of these rules in distinguishing between benign and malignant tumors by correlating the findings with histopathology reports.

MATERIAL AND METHODS

This prospective observational study was conducted at the Department of Gynecology and Radiology of Army Hospital R&R, New Delhi from Aug 2020 to July 2022. Ethical approval has been obtained from the Ethical Approval Committee of Army Hospital R&R, New Delhi.

Study Population :

The study population consisted of women of all age groups attending the Obstetrics & Gynecology Department with a palpable pelvic mass. Informed consent was obtained from all participants. The inclusion criteria included women with ovarian masses, while pregnancy, a history of previous cancer and non ovarian masses were excluded. The sample size was based on a study by Timmerman et al. (2010), reporting a 92% sensitivity of IOTA-SR in predicting malignancy in ovarian masses, with a prevalence of 28%.

Data Analysis :

Data analysis was conducted using SPSS version 17.0. Continuous variables are presented as mean ± SD, while categorical variables are shown as absolute numbers and percentages. Normality of data was checked before analysis. Categorical variables were analyzed using chi-square or Fisher's exact test. Receiver operating characteristics (ROC) analysis determined optimal cut-off values for CA-125, CEA, CA 19-9, LDH, and IOTA. Diagnostic accuracy was evaluated using sensitivity, specificity, and predictive values, with a p-value of less than 0.05 indicating significance.

RESULT

The study revealed that the mean age of the patients was 38.06 ± 8.68 years, ranging from 23 to 63 years, with a median age of 38 years (IQR: 31.50 - 43). The mean weight was 59.32 ± 9.85 kg, with a minimum of 45 kg and a maximum of 88 kg, and a median of 58 kg (IQR: 52 - 65.50). The mean height was 152.86 ± 9.14 cm, ranging from 130 to 170 cm, with a median height of 156 cm (IQR: 147 - 160).

Table 1: Mean CA 125 , CEA, CA 19.99, AFP and LDH of the Patients

	Mean ± SD	Min - Max	Median (IQR)
CA 125 UNITS/ml	135.84 ± 390.27	8 - 2500	28.50 (8 - 55)
CEA [ng/ml]	1.52 ± 1.06	0.10 - 5.40	1.26 (0.72 - 1.84)
CA19.99 [U/ml]	21.80 ± 16.54	3.28 - 95.00	18 (11.15 - 26.75)
AFP [ng/ml]	1.06 ± 21.00	1.06 - 21.00	13 (4 - 16.25)
LDH [IU/L]	227.12 ± 55.74	135 - 333	214.50 (185.25 - 265)

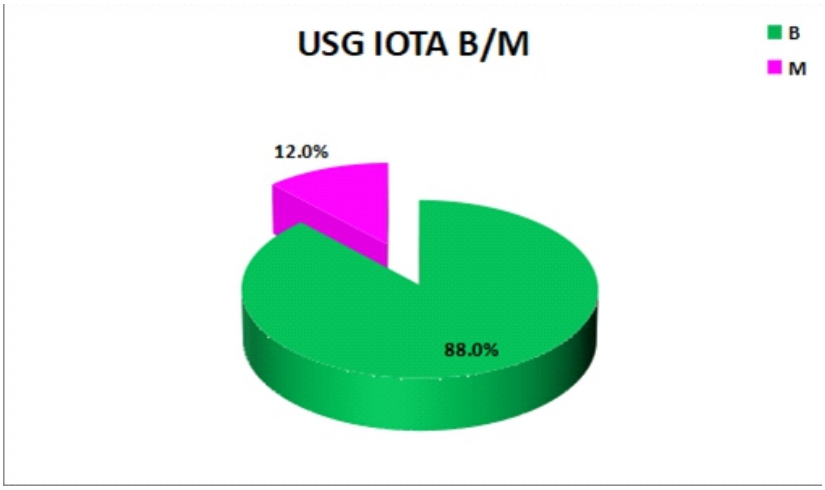

Figure 1: Distribution of Patients According to USG IOTA B/M

The distribution of patients based on the site showed that 50% had the condition on the right side, 48% on the left side, and 2% on both sides, with a total of 50 patients. Regarding the final diagnosis, 82% of the patients were diagnosed with condition B, while 18% were diagnosed with condition M, bringing the total to 50 patients.

Table 2 : Final Diagnosis

Final diagnosis	Frequency	%
B/L Serous borderline tumor with invasion	2	4.0%
Borderline Serous Carcinoma	1	2.0%
Endometriosis	3	6.0%
Endometriotic cysts	13	26.0%
Fibroma	1	2.0%
Fibroma Ovary	3	6.0%
Haemmorhagic Ovarian cyst	1	2.0%
High grade serous carcinoma	6	3.0%
Mature Teratoma	2	4.0%
Mature Teratoma with mucinous cystadenoma	2	4.0%
Mucinous Cystadenoma	2	4.0%
Seromucinous cystadenoma	2	4.0%
Serous cystadenoma	12	24.0%
Total	50	100%

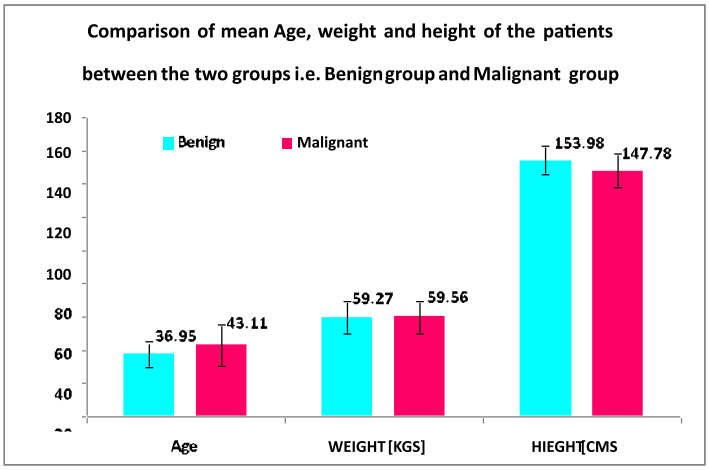

Figure 2: Comparison of Mean Age, Weight and Height of the Patients Between the Two Groups i.e. Benign Group and Malignant group

Table 3 : Comparison of CA 125 , CEA, CA 19.99, AFP and LDH of the patients between the two groups i.e. Benign group and Malignant group

	Final Diagnosis						p value
	Benign			Malignan			
	Mean ± SD	Min – Max	Median (IQR)	Mean ± SD	Min - Max	Median (IQR)	
CA 125 UNITS/ml	28.15 ± 19.19	8 - 75	25 (8 - 40)	626.44 ± 775.15	8 - 2500	500 (65 - 800)	0.001*
CEA [ng/ml]	1.57 ± 1.13	0.4 - 5.4	1.30 (0.72 - 1.86)	1.28 ± 0.68	0.30 - 2.20	1.08 (0.7 - 1.9)	0.705
CA19.99 [U/ml]	21.90 ± 16.67	3.28 – 95	18 (11.1 - 27.5)	21.36 ± 16.91	4.00 - 60.00	18 (9 - 28)	0.960
AFP [ng/ml]	11.40 ± 6.41	1.06 – 20	14 (3.8 - 16.0)	12.58 ± 6.35	2.18 - 21.00	13 (7.50 - 18)	0.771
LDH [IU/L]	227.8 ± 54.49	145 – 333	213 (188 - 269)	224 ± 64.57	135.0 - 133.0	222 (177 - 279)	0.771

*signifies significant p value<0.05

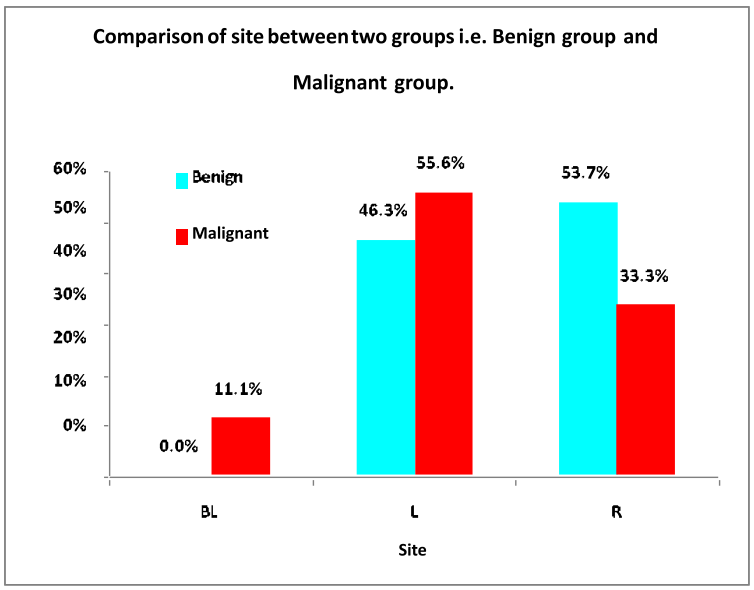

Figure 3: Comparison of site between two Groups i.e. Benign Group and Malignant Group

Table 4 : Correlation Between Diagnosis According to USG IOTA and Final Diagnosis

USG IOTA B/M	Final Diagnosis				p value
	Benign		Malignant		
	Frequency	%	Frequency	%	
Benign	40	97.6%	4	44.4%	0.001*
Malignant	1	2.4%	5	55.6%	
Total	41	100%	9	100%	

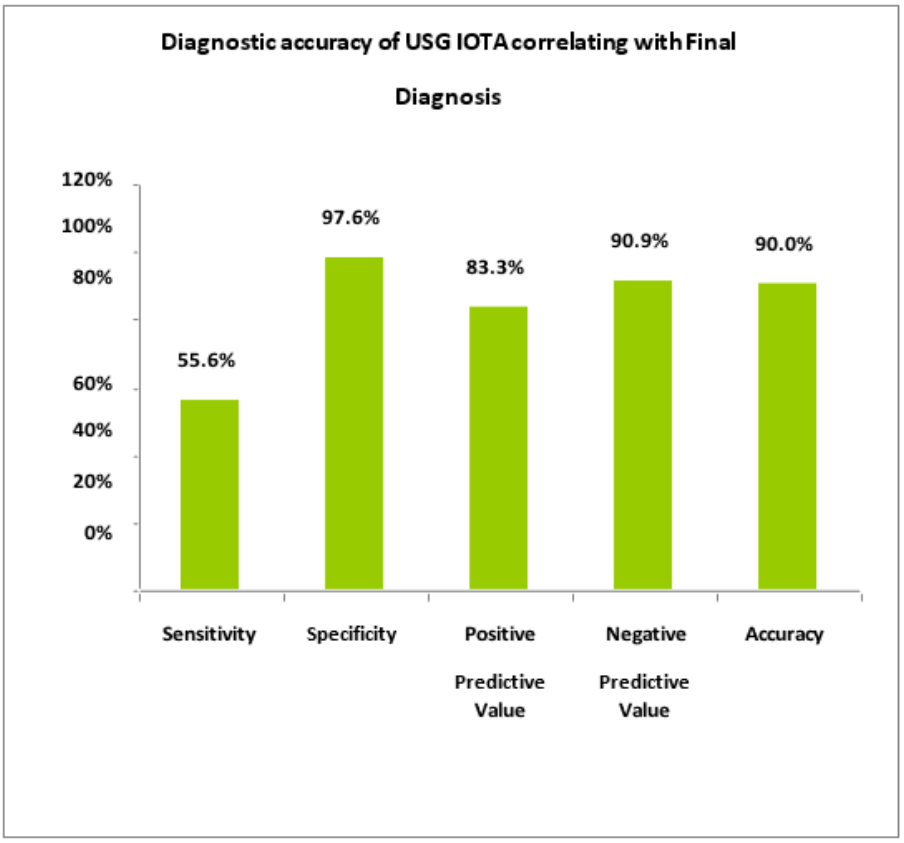

Figure 4: Diagnostic Accuracy of USG IOTA Correlating with Final Diagnosis

Table 5: Receiver Operating Curve of USG IOTA

Area Under the Curve				
Test Result Variable(s): USG IOTA				
Area	Std. Error[a]	Asymptotic Sig.[b]	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
0.766	0.107	0.013	0.555	0.976

Table 6: Receiver Operating Curve of Parameters

Area Under the Curve					
Test Result Variable(s)	Area	Std. Error[a]	Asymptotic Sig.[b]	Asymptotic 95% Confidence Interval	
				Lower Bound	Upper Bound
CA 125 UNITS/ml	0.890	0.09	<0.001**	0.714	1.000
CEA [ng/ml]	0.459	0.104	0.705	0.255	0.664
CA19.99 [U/ml]	0.495	0.107	0.960	0.285	0.704
AFP [ng/ml]	0.531	0.109	0.772	0.318	0.744
LDH [IU/L]	0.469	0.118	0.772	0.237	0.701

**signifies highly significant p value<0.001

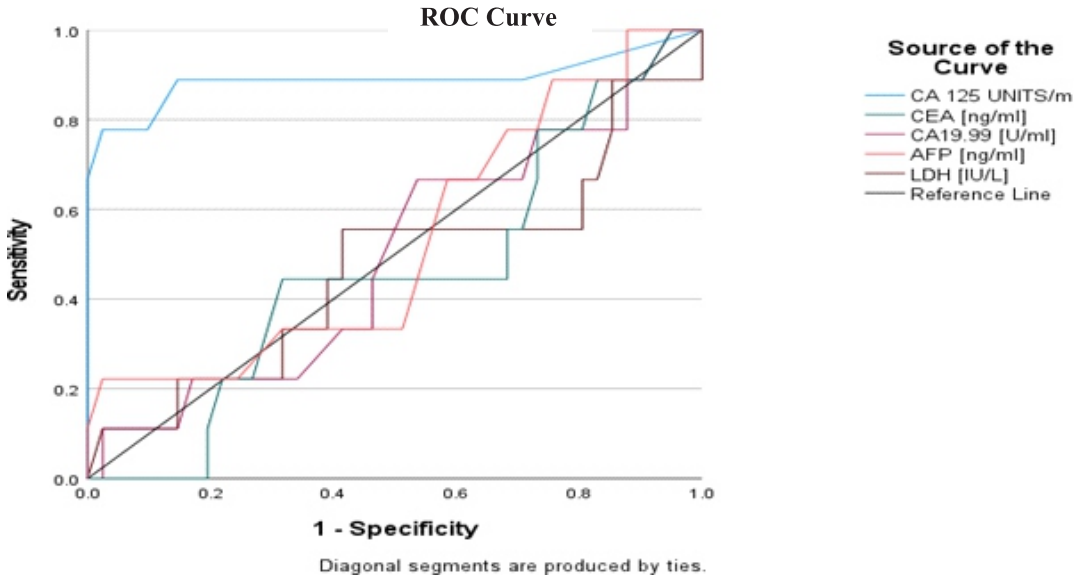

Figure 5: Receiver Operating Curve of Various Parameters

DISCUSSION

Ovarian cancer remains one of the leading causes of death among women despite advancements in early detection and treatment. Few studies have systematically evaluated the effectiveness of the International Ovarian Tumor Analysis (IOTA) guidelines for assessing adnexal masses, and the current study aims to contribute to this gap. The primary goal is to determine the sensitivity and specificity of the IOTA simple rules in distinguishing between benign and malignant ovarian tumors. This prospective study correlates the IOTA findings with final histopathological results to assess the accuracy of the IOTA approach [16,17].

The study was conducted over two years at the Gynecology OPD and Radiology Department of Army Hospital R&R in New Delhi. A total of 50 patients selected according to specific inclusion and exclusion criteria, participated in the study. These criteria ensured that all patients had a palpable pelvic mass but excluded those with previous cancer, pregnancy, or non-ovarian masses [18].

Patients were evaluated based on various characteristics including mean age, weight, and height. The average age of participants was 38.06 years, with a standard deviation of 8.68 years, and the average weight and height were 59.32 kg and 152.86 cm, respectively. Comparative studies have reported slightly different age distributions, with other research observing mean ages ranging from the mid-30s to the late 40s. These differences could be attributed to the varying demographics of the study populations [19].

The study also examined specific tumor markers such as Cancer Antigen 125 (CA 125), Carcino-Embryonic Antigen (CEA), CA 19.99, Alpha-Fetoprotein (AFP), and

The distribution of patients according to the IOTA classification showed that 88% had benign ovarian masses and 12% had malignant ones. This pattern aligns with previous findings, which also indicate a higher prevalence of benign cases compared to malignant ovarian cancer.

When examining the anatomical site of the masses 50% of the cases were located on the right side, 48% on the left, and only 2% had bilateral involvement. These findings underscore the predominance of unilateral ovarian masses in the study population.

Histopathological diagnosis revealed that the majority of patients (82%) had benign tumors, while 18% had malignant tumors. These findings align with other research, such as Tolani et al. (2020), which reported similar proportions of benign and malignant cases. The benign cases in this study included a range of conditions, such as endo-metriotic cysts (26%), serous cystadenomas (24%), and mucinous cystadenomas (4%). Malignant cases included high-grade serous carcinoma (12%) and borderline serous tumors (4%) [21].

A comparison of demographic and tumor marker data between benign and malignant groups showed interesting trends. Patients in the malignant group had a higher mean age (43.11 years) compared to those in the benign group (36.95 years), though the difference was not statistically significant. Similarly, the mean weight and height were comparable between the two groups, with no significant differences observed. However, a notable finding was the significant difference in CA 125 levels between the two groups. The malignant group had a much higher mean CA 125 level (626.44 units/ml) compared to the benign group (28.15 units/ml), indicating that CA 125 can be a valuable marker in differentiating between benign and malignant ovarian masses. However, other markers, such as CEA, CA 19.99, AFP, and LDH, did not show significant differences between the two groups.

The study also evaluated the distribution of ovarian masses based on their anatomical site in both benign and malignant groups. The majority of patients in the benign group had unilateral masses, while a small percentage of the malignant group had bilateral masses. However the difference in site distribution was not statistically significant.

A key part of the study involved correlating the IOTA ultrasound results with the final histopathological diagnosis. In the benign group, 97.6% of patients were correctly classified as benign by the IOTA rules, while in the malignant group, 55.6% were accurately classified as malignant. This highlights the high specificity of the IOTA rules in identifying benign masses, though the sensitivity for detecting malignancy was moderate [22].

The study evaluated the diagnostic accuracy of the IOTA rules, finding a sensitivity of 55.6%, specificity of 97.6%, positive predictive value (PPV) of 83.3%, negative predictive value (NPV) of 90.9%, and overall accuracy of 90%. These findings align with other research, which similarly highlights the IOTA rules' high specificity but moderate sensitivity in detecting ovarian malignancies [23].

Receiver operating characteristic (ROC) analysis further supported the value of CA 125 as a diagnostic marker. The area under the curve (AUC) for CA 125 was 0.890, indicating a strong ability to differentiate between benign and malignant cases. However, other markers such as CEA, CA 19.99, AFP, and LDH did not show significant diagnostic value based on their ROC analysis [24].

This study demonstrated the effectiveness of the IOTA simple rules in distinguishing between benign and malignant ovarian masses, particularly in combination with tumor markers like CA 125. The high specificity of the IOTA approach makes it a valuable tool for ruling out malignancy, though its moderate sensitivity suggests that it should be used in conjunction with other diagnostic methods to ensure accurate detection of ovarian cancer [25].

CONCLUSION

Our study confirms the effectiveness of the IOTA simple ultrasound rules in diagnosing ovarian tumors, conducted over two years with 50 patients. The mean patient age was 38.06 years, and CA 125 was significantly elevated in malignant cases. Sensitivity was 55.6%, specificity 97.6%, and overall accuracy 90%. Combining CA 125 measurements with ultrasound characteristics improved diagnostic accuracy, highlighting the importance of integrating multiple diagnostic tools for more accurate ovarian cancer detection.

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