

ORIGINAL RESEARCH

Evaluation of Iota Adnex Model to Distinguish Benign and Malignant Ovarian Tumor

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Received date: 23 February, 2024

Acceptance date: 27 March, 2024

ABSTRACT

Background: Ovarian cancer poses a significant challenge in diagnosis due to its nonspecific symptoms and lack of effective screening tools. The International Ovarian Tumour Analysis (IOTA) developed the multiclass Assessment of Different NEoplasias in the adneXa (ADNEX) model for early diagnosis and screening. This study aimed to evaluate the efficacy of the IOTA ADNEX model in distinguishing between benign and malignant ovarian masses. **Methods:** A prospective analytical study was conducted at a tertiary care hospital from February 2020 to January 2021. Clinical and ultrasound data were collected from 107 women with ovarian masses. The IOTA ADNEX model was used to predict the nature of masses, which were then confirmed through histopathological examination. Statistical analysis was performed to assess the model's diagnostic accuracy. **Results:** The mean age of patients was 38.14 years, with the majority presenting with abdominal pain and abdominal distension. Serum CA125 levels and ultrasound findings significantly differed between benign and malignant masses according to the IOTA ADNEX model. Histopathological examination confirmed the model's accuracy in predicting mass nature, with a sensitivity of 91.36%, specificity of 96.15%, and diagnostic accuracy of 92.52%. **Conclusion:** The IOTA ADNEX model demonstrated high diagnostic accuracy in distinguishing between benign and malignant ovarian masses. Its simplicity and effectiveness make it a valuable tool for preoperative diagnosis and management planning, aiding in timely and appropriate treatment decisions for women with ovarian masses.

Keywords- IOTA ADNEX model, Benign Ovarian Tumor, Malignant Ovarian Tumor, Histopathological examination

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INTRODUCTION

The development of cancer is attributed to mutations resulting from environmental factors, errors in DNA replication, or genetic inheritance [1]. Carcinogenesis is strongly associated with the process of ageing [2]. Cancer is identified as the primary or secondary cause of death in 91 out of 172 countries,[3] and it ranks third or fourth in the remaining 22 countries. [4]Cancer ranks as the second most common cause of death in urban areas and the fourth most common cause of death in rural areas in India [5]. Gynaecologists commonly encounter ovarian tumours, and it is crucial to accurately diagnose these masses before proceeding with surgical or non-surgical treatment. The success of care and management depends on a comprehensive understanding of the specific type of tumour.

Several researchers have attempted to create a thorough screening tool, but its effectiveness was

hindered by subpar performance, resulting in a lack of optimisation [6]. Gynaecologists face difficulties in accurately diagnosing ovarian cancer due to the manifestation of symptoms in an atypical and nonspecific manner [7]. At first, ovarian cancers can be identified by detecting abnormal growths in the adnexa. The most precise and reliable prognosis of the disease can be obtained through laparotomy or laparoscopy with histopathology [8]. The survival rate of patients significantly improves when there is a thorough understanding of the high risk of malignancy, stage, and type of cancer, particularly before surgery. A considerable number of individuals seek medical attention at local or primary health centres due to the presence of adnexal masses and accompanying non-specific symptoms. Prior to the surgery, it is essential to make important decisions regarding the treatment plan for these patients, including whether to proceed with the operation and

determining the specific type and scope of the procedure [9-11]. Previous data regarding the nature of the tumour (benign or malignant) will aid in more effective patient care. By utilising a reliable method to evaluate pelvic masses or adnexal masses, a greater number of patients can receive initial treatment during the early phases, thereby decreasing both mortality and morbidity rates. Nevertheless, there are currently no existing population-based screening tools accessible for the disease. There is a pressing requirement for a highly accurate and reliable tool to diagnose ovarian cancer in patients [8].

Serum CA-125, a specific tumour marker, is essential for the diagnosis of ovarian cancer. A limited number of studies have discovered that 85% of cases of epithelial ovarian cancer exhibit an increase in the concentration of this marker, with a threshold level of 35 U/ml [11]. This marker is relied upon by various software programmes, scoring systems, and mathematical models. Furthermore, the use of the Serum CA-125 marker, ultrasonographic findings, CT scans, and triage with MRI aided in accurately differentiating between benign and malignant ovarian cancer [12]. Gynecologic ultrasonography is the predominant method used to detect the presence of ovarian masses [13]. This technology not only detects the presence of any type of mass, but also distinguishes between benign and malignant tumours. Moreover, the IOTA-ADNEX model is employed to ascertain the appropriate treatment plan and course of action for various neoplasms in the adnexa. Moreover, the IOTA-ADNEX model is utilised to ascertain the treatment strategy and course of action, enabling the gynaecologist to minimise both mortality and morbidity. It is noteworthy that ovarian malignancies are infrequent among gynecologic tumours, but they are alarming due to their high fatality rate and likelihood of recurrence. However, the use of ultrasonography for early detection enhances the patient's chances of survival, thereby offering a cost-effective approach to treatment and follow-up [14].

Various scoring tools and techniques, such as the Risk of Malignancy Index (RMI) and the Risk of Ovarian Malignancy Algorithm (ROMA), have been developed to detect adnexal masses and classify them as either benign or malignant. In 2005, the IOTA group created numerous algorithmic risk predictive models. Logistic Regressions 1 and 2 (LR1 and LR2) are enhanced models developed by incorporating sonographic characteristics of Simple Rules and LR. The predictive models exhibited superior performance in comparison to any previously developed models. In 2014, IOTA developed the ADNEX model, which exhibited enhanced performance compared to previous models. The risk model provides comprehensive information about the tumour, including its benign or malignant nature, as well as its stage and type of cancer, such as borderline, Stage I, Stages II-IV, and secondary metastatic [14].

MATERIALS AND METHODS

The present study was conducted as a prospective analytical study at Department of Obstetrics and Gynaecology, Gandhi medical college and associated Sultania Zanana Hospital, Bhopal from 1st February 2020 to 31st January 2021. Women admitted in Sultania Zanana Hospital for ovarian masses were included while those whom were refused for ultrasonography, pregnant at the time of presentation, ectopic pregnancy and those who refused to be a part of this study, were excluded from the study. Written consent was obtained from all the study participants after explaining them nature and purpose of study with the help of participant information sheet. They were ensured that confidentiality will be maintained and option to withdraw from the study was always kept open. The study was approved by Institutional ethical committee. All the women presenting with ovarian masses and fulfilling the inclusion criteria and willing to participate in the study were enrolled. Careful and detailed history was elicited including age, parity, socioeconomic status, age of menarche, menopausal status, family history of ovarian or breast cancer, history of treatment taken for infertility was obtained and entered in questionnaire.

Then all patients were subjected to clinical and pelvic examination and routine workup including haemoglobin, blood group, blood sugar level, HIV, HbsAg, VDRL, coagulation profile, Liver function test, Renal function test, serum CA-125 levels, ultrasonography whole abdomen and pelvis, transvaginal sonography. CT scan and MRI was done in patients when indicated. Patients were taken for surgical procedure. According to benign or malignant nature of tumor and extent of the disease, operative procedure was done. Surgical specimen obtained was sent for histopathological examination. Histopathological findings were used as a gold standard. Trans-abdominal Ultrasonography performed in patients with full bladder or Trans-Vaginal Ultrasonography performed in patients after emptying the bladder.

Ultrasound findings were assigned as follows:

1. The maximal diameter of lesion (mm)
2. Maximal diameter of largest solid part of lesion (mm)
3. Number of papillary projections (0,1,2,3,>3)
4. Presence of more than 10 locules (yes/no)
5. Acoustic shadows (yes/no)
6. Presence of ascites (yes /no)

Age (in year), serum CA 125 (U/ml), type of centre (oncology versus other hospital centres) and ultrasonographic findings of each patient were assessed and analysis done by using IOTA ADNEX model.

IOTA ADNEX model differentiate between benign and four types of malignant tumor on the basis of three clinical parameters (age, serum CA 125, type of centre) and six ultrasound parameters as mentioned above. After surgery, histo-pathological findings of

excised tumor were analyzed to determine final diagnosis. Finally, role of IOTA ADNEX Model in preoperative evaluation of ovarian masses was seen and its correlation with histo-pathological findings was determined.

Statistical method: Sample size included all patients admitted at Sultania Zanana Hospital with ovarian masses. Nonparametric test was analyzed by Chi Square test or Mann Whitney U test. P value less than

0.05 was considered significant. Both descriptive and inferential statistics were used to identify the features and characteristics of the data. Continuous variables were expressed as mean \pm standard deviation. Non-continuous variables were expressed as number of occurrences and percentage. One-way ANOVA was carried out to observe the significance of mean if data found to be normal.

RESULTS

Table 1: Distribution of patients according		
Age group (Years)	Frequency	Percentage
≤ 20	11	10.28%
21-30	26	26.10%
31-40	33	30.84%
41-50	22	20.56%
51-60	09	8.41%
61-70	06	5.60%
Grand Total	107	100.00%
Mean Age	38.14	
Socioeconomic status		
Lower	64	59.81%
Middle	23	21.49%
Upper	20	18.69%
Grand Total	107	100.00%
Marital status		
Married	94	87.85%
Unmarried	13	12.15%
Grand Total	107	100.00%
Chief Complaints		
Abdominal pain	68	63.55%
Abdominal distension	36	33.64%
Abdominal lump	28	26.16%
Amenorrhea	2	1.86%
Vomiting	3	2.80%
Postmenopausal bleeding	1	0.93%
Backache	1	0.93%
Menstrual History		
Regular	74	69.16%
Irregular	19	17.76%
Postmenopause	14	13.08%
Grand Total	107	100.00%
Parity		
Nulliparous	30	28.03%
P1	24	22.42%
P2	18	16.83%
P3	19	17.75%
>P4	16	14.97%
Risk factors		
1) BMI		
$\leq 30 \text{ kg/m}^2$	92	85.99%
$> 30 \text{ kg/m}^2$	15	14.01%
2) Nulliparity	30	28.03%
3) Smoking	12	11.21%
4) History of infertility treatment	7	6.54%
5) Late menopause	6	5.60%
6) Family history of Ovarian cancer	5	4.67%

7)Late child birth>35yr	4	3.73%
8)Tobacco intake history	3	2.80%
9)Family history of Breast cancer	2	1.86%
10)HRT	1	0.93%
11)No risk factors	20	1.86%

The provided table outlines demographic and clinical characteristics of 107 patients, with various gynecological concerns. The mean age of the cohort is approximately 38 years, with a distribution spanning across different age groups, most notably in the 31-40 age. Socioeconomically, the majority fall within the lower stratum. Most patients are married and present with chief complaints of abdominal pain, abdominal distension, and abdominal lump. Menstrual history indicates a predominance of regular cycles, while

parity distribution ranges from nulliparous to higher parity, with nulliparity being the most common. Various risk factors for gynecological conditions are identified, including high BMI, nulliparity, and smoking, among others. This comprehensive overview provides insight into the demographic and clinical profile of the patient population under study, essential for understanding and addressing their healthcare needs effectively.

Serum CA125(U/ml)	Frequency	Percentage
<35	47	43.93%
35-200	56	52.34%
>200	4	3.74%
Grand Total	107	100.00%

Table 2 presents the distribution of 107 patients based on their serum CA125 levels. The majority of patients (43.93%) have serum CA125 levels below 35 U/ml, while 52.34% fall within the range of 35-200 U/ml. A smaller proportion (3.74%) of patients exhibit elevated serum CA125 levels exceeding 200 U/ml.

This categorization provides valuable insight into the distribution of CA125 levels within the patient population, which is clinically significant for assessing potential diagnoses and monitoring disease progression, particularly in gynecological conditions.

	BENIGN (n=81)	MALIGNANT (n=26)	P value
1)Serum CA125(U/ml)	48.87±16.81	128.49±48.22	<0.001
2) USG findings			
• Maximum diameter of lesion(mm)	94.08±56.12	158.03±71.42	<0.001
• Maximum diameter largest solid part of lesion(mm)	17.71± 31.12	62.17±21.32	<0.001
• Locules>10	14(53.84%)	26(100%)	0.022
• Acoustic shadows	9(11.11%)	8(30.77%)	0.567
• Ascites	22(27.16%)	23(88.46%)	0.884
• Number of Papillae			
0	64(79.01%)	6(23.07%)	0.023
1	3(3.71%)	3(11.54%)	
2	6(7.41%)	3(11.54%)	
3	2(2.46%)	1(3.85%)	
>3	6(7.41%)	13(50%)	

Table 3 presents findings according to the IOTA ADNEX model, comparing patients with benign (n=81) and malignant (n=26) conditions. Significant differences were observed between the two groups across various parameters. Patients with malignant conditions exhibited notably higher levels of serum CA125 (128.49 U/ml) compared to those with benign conditions (48.87 U/ml), with a significant p-value of <0.001. Additionally, ultrasound findings revealed substantial disparities in lesion characteristics,

including the maximum diameter of the lesion and the largest solid part of the lesion, both significantly larger in malignant cases. Malignant lesions also demonstrated a higher prevalence of locules exceeding 10, absence of papillae, and the presence of ascites compared to benign cases, with corresponding p-values indicating statistical significance. These findings underscore the utility of the IOTA ADNEX model in distinguishing between benign and malignant ovarian lesions based on clinical and

ultrasound characteristics, aiding in accurate diagnosis and treatment decisions.

Benign	81	75.70%
Malignant	26	24.30%

The classification of ovarian masses according to the IOTA ADNEX model demonstrates a predominant presence of benign masses, comprising 75.70% of cases. Conversely, malignant masses represent a smaller yet significant proportion, accounting for

24.30% of the cohort. This distribution underscores the utility of the IOTA ADNEX model in distinguishing between benign and malignant ovarian masses, facilitating appropriate clinical management and treatment decisions.

Unilateral Salpingo-oophorectomy with comprehensive surgical staging	51	47.67%
TAH with Bilateral Salpingo-oophorectomy with comprehensive surgical staging	39	36.44%
TAH with Bilateral Salpingo-oophorectomy with debulking	14	13.09%
Debulking and chemotherapy	3	2.80%

The distribution of patients based on interventions administered reveals diverse treatment modalities employed in managing ovarian conditions. The most common intervention, observed in 47.67% of cases, involves Unilateral Salpingo-oophorectomy with comprehensive surgical staging, indicating a focus on targeted surgical removal with thorough assessment. Following closely, TAH (Total Abdominal Hysterectomy) with Bilateral Salpingo-oophorectomy and comprehensive surgical staging is administered in 36.44% of cases, suggesting a more extensive surgical approach. A smaller yet notable proportion,

comprising 13.09% of patients, undergoes TAH with Bilateral Salpingo-oophorectomy with debulking, highlighting the importance of tumor reduction procedures alongside organ removal. Additionally, a minority of cases (2.80%) receive a combined treatment strategy involving debulking and chemotherapy, indicating a multidisciplinary approach to managing advanced or aggressive conditions. This distribution underscores the tailored and varied nature of interventions in addressing ovarian pathologies, aiming for optimal patient outcomes through comprehensive treatment strategies.

BENIGN		
Papillary Serous Cystadenoma	24	22.42%
Benign Mature Cystic Teratoma	23	21.49%
Simple Ovariancyst	15	14.01%
Mucinouscystadenoma	10	9.34%
Chocolatecyst	1	0.93%
Brenner tumour	2	1.87%
BORDERLINE		
Endometrioid Borderline Ovarian Tumour	1	0.93%
Borderline Mucinous Tumour	3	2.80%
Serous borderline ovarian tumour	1	0.93%
MALIGNANT		
Papillary Serous Adenocarcinoma	15	14.01%
Mucinous adenocarcinoma	5	4.67%
Granulosa Cell Tumour	2	1.87%
Sero-mucinous Adenocarcinoma	2	1.87%
Left Krukenberg	2	1.87%
Endometrioid Adenocarcinoma	1	0.93%

The histopathological report delineates a comprehensive spectrum of ovarian pathologies encountered among patients. Among benign lesions, Papillary Serous Cystadenoma and Benign Mature Cystic Teratoma are the most prevalent, accounting for 22.42% and 21.49% of cases, respectively. Simple Ovarian Cysts and Mucinous Cystadenomas follow closely, constituting 14.01% and 9.34% of diagnoses,

respectively. Less frequently observed benign conditions include Chocolate Cysts and Brenner Tumors. Borderline lesions, though less common, present a variety of histological subtypes, with Endometrioid Borderline Ovarian Tumors and Borderline Mucinous Tumors being the primary entities identified. Malignant lesions encompass a range of aggressive tumors, with Papillary Serous

Adenocarcinoma and Mucinous Adenocarcinoma representing the most prevalent malignant diagnoses, each comprising 14.01% and 4.67% of cases, respectively. Granulosa Cell Tumors, Sero-mucinous Adenocarcinomas, and Krukenberg Tumors are also identified, albeit with lower frequency. This

comprehensive overview underscores the diverse histopathological landscape of ovarian pathologies encountered, highlighting the importance of accurate diagnosis and tailored treatment strategies for optimal patient management and outcomes.

Findings	Frequency	Percentage
Benign	75	70.09%
Malignant	32	29.91%
Grand Total	107	100%

Table 7 outlines the classification of ovarian masses based on histopathological reports, encompassing 107 cases. Among these, 75 masses (70.09%) were identified as benign, while 32 masses (29.91%) were determined to be malignant. This distribution highlights the prevalence of benign ovarian masses

within the patient population studied, though a significant proportion also exhibited malignant pathology. This classification provides crucial insight into the nature of ovarian masses encountered, guiding appropriate management strategies and prognostic considerations.

VARIABLES		BENIGN (n=75)	MALIGNANT (n=32)				Pvalue
			Borderline (05)	Ovarian metasta sis (02)	Stage 1 (14)	Stage 2-4 (11)	
Age	Mean ± SD	32.09±12.76	45± 19.97	64.50±2.1 2	53.50±10.65	50.25±11.2 0	<0.00 1
Menstrual History	Irregu lar	12 (16%)	1 (20%)	0 (0)	3(21.4%)	3 (33.3%)	0.001
	Meno pau se	6 (8%)	0 (0)	1 (50%)	7 (50%)	0 (0)	
	Regul ar	57 (76%)	4 (80%)	1 (50%)	4(28.6%)	8 (66.7%)	
CA 125 (U/mL)		31.24±51.84	46.64±49.04	23.37±3.6 6	190.98±256. 97	80.65±43.0 4	<0.00 1
Maximum diameter of lesion (mm)		97.03±64.99	181.60±135. 69	120±15.5 5	132.26±108. 18	129.14±64. 46	0.076
Maximum diameter of largest solid component, if present (mm)		19.58±24.66	78.20±89.61	25±5.65	40.82±25.82	49.13±44.2 0	<0.00 1
Papillaryproj ections present	0	61 (82.4%)	2 (40%)	2(100%)	3(21.4%)	2 (16.7%)	<0.001
	1	3 (4%)	0 (0)	0 (0)	3(21.4%)	0 (0)	
	2	6 (8.1%)	0 (0)	0 (0)	1 (7.1%)	2 (16.7%)	
	3	2 (2.7%)	0 (0)	0 (0)	0 (0)	1 (8.3%)	
	>3	3 (4.1%)	3 (60%)	0 (0)	7 (50%)	6(58.3%)	
> 10 cyst locules		13(17.33%)	5 (100%)	2(100%)	10(71.4%)	10(90.9%)	<0.001
Acoustic shadows		7 (6.5%)	2 (1.9%)	0 (0)	4 (3.7%)	4 (3.7%)	0.055
Ascites		15 (14%)	5 (4.7%)	2(1.9%)	13(12.1%)	10 (9.3%)	<0.001

Table 8 provides clinical characteristics and ultrasound findings in women with adnexal masses categorized by tumor subclassification according to histopathology. The benign group consists of 75

cases, while the malignant group includes 32 cases classified as borderline, ovarian metastasis, stage 1, and stage 2-4. In terms of age, there's a notable difference between the benign and malignant

subgroups, with mean ages ranging from 32.09±12.76 years in benign cases to 50.25±11.20 years in stage 2-4 malignant cases (P<0.001). Menstrual history also shows significant differences, with irregular menstruation being more common in malignant cases compared to benign cases (P=0.001).

Serum CA125 levels varied significantly across subgroups, with the highest levels observed in stage 1 malignant cases (190.98±256.97 U/mL) compared to other subgroups (P<0.001). Ultrasound findings revealed differences in the maximum diameter of lesions and the maximum diameter of the largest solid component, with malignant cases generally exhibiting

larger measurements compared to benign cases (P<0.001). Additionally, the presence of papillary projections was significantly associated with malignancy (P<0.001). Other ultrasound characteristics such as >10 cyst locules and the presence of ascites were also more common in malignant cases compared to benign cases (P<0.001). However, the presence of acoustic shadows did not show a significant difference between the two groups (P=0.055). Overall, these findings highlight the utility of clinical and ultrasound characteristics in distinguishing between benign and malignant adnexal masses, aiding in appropriate management decisions.

HPR	IOTA ADNEX Model		Grand Total	P value
	Benign	Malignant		
Benign	74	1	75	0.001
Malignant	7	25	32	
Grand Total	81	26	107	

Table 9 illustrates the association between Histopathological Report (HPR) and findings from the IOTA ADNEX Model. The table shows that out of the 75 cases IOTA ADNEX Model, reported 74 as benign, while one as malignant (P value=0.001). In contrast, among the 32 cases classified as malignant by the

HPR, 25 were confirmed as malignant by IOTA, and 7 were classified as benign. The association between HPR and the IOTA ADNEX Model findings is statistically significant with p value 0.001 indicating a strong relationship between the two classification methods.

Parameters	Values	95% CI
Sensitivity	91.36%	83.00% to 96.45%
Specificity	96.15%	80.36% to 99.90%
PPV	98.67%	91.54% to 99.80%
NPV	78.12%	63.66% to 87.92%
Diagnostic accuracy	92.52%	85.80% to 96.72%

Table 10 presents the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy of the IOTA ADNEX Model along with their respective 95% confidence intervals (CI).

These metrics indicate the performance of the IOTA ADNEX Model in correctly identifying both benign and malignant cases. It demonstrates high sensitivity, specificity, PPV, and diagnostic accuracy, indicating its effectiveness in distinguishing between benign and malignant adnexal masses. However, the NPV suggests a relatively lower ability to accurately identify benign cases compared to malignant ones.

DISCUSSION

The study included a total of 107 women who presented with ovarian masses. The average age of the patients in our study was 38.14± 15.58 years, with a range of 14 to 67 years. The majority of women fell within the age range of 31-40 years, accounting for 30.84% of the total. This was followed by the age range of 21-30 years, which accounted for 26.10% of the total. The age range of 41-50 years accounted for

20.56% of the total. This statement succinctly explains that ovarian masses are predominantly observed in individuals of reproductive age group. The study conducted by Chen H et al. (2019) found that the average age of patients with benign ovarian masses was 41 years, while for malignant cases, it was 51 years. The average age in borderline ovarian cancer, stage I ovarian cancer, stage II-IV ovarian cancer, and ovarian metastasis was 47, 50, 58, and 47 years, respectively.[15] A study conducted by Dr. Erdogan Nohuzetal(2018) examined a group of postmenopausal women between the ages of 50 and 85. The average age of the participants was found to be 62.45 ± 8.93 standard deviation.[16] In a study conducted by Soo Young Jeong et. al (2020), the average age of the patients was 45 years, with a range of 20 to 71 years.[17] In a separate study conducted by Shetty J et.al(2019), the average age of the patients was 37.5 years, with a range of 15 to 72 years. [18]Our study revealed that the lower socio-economic status was predominant among women, with 64 individuals (59.81%) falling into this category. The middle socio-economic class accounted for 23

individuals (21.49%). Out of the total population, 20 women, accounting for 18.69%, belong to the upper socio-economic class. Our study revealed that out of the total number of women, 94 (equivalent to 87.85%) were married. Out of the total, only 13 individuals, accounting for 12.15% of the group, were not married. Given that a significant proportion of women in our society are already married, it follows that the majority of cases of ovarian masses occur in married women. During the initial phase, the majority of women do not show any symptoms or present with nonspecific complaints. Approximately 30% of patients exhibit multiple complaints.

Our study revealed that abdominal pain was the predominant complaint among 63.55% of the 68 women included in our analysis. Abdominal distension was the second most common complaint reported by 36 women, accounting for 33.64% of the cases. A total of 28 women, accounting for 26.16% of the participants, reported experiencing an abdominal lump. Several women are experiencing symptoms such as vomiting, amenorrhoea, postmenopausal bleeding, and backache. In this study out of 107 patients, 74 women (69.16%) reported having a regular menstrual cycle, while 19 women (17.76%) had a history of irregular menstruation. Additionally, 14 women (13.08%) had reached menopause. These findings indicate that ovarian masses are more prevalent in premenopausal women and are predominantly noncancerous. Several studies, including those conducted by Chen H et al (2019)[15], Soo Young Jeong (2020)[16], Tudor Butureanu, T et al. (2021)[19], and Jyothi Shetty et al (2019)[18], have found that a greater proportion of premenopausal women have ovarian masses compared to postmenopausal women. In the present study, the examination of obstetric history revealed that only 30 women (28.03%) were nulliparous. A total of 71.97% of individuals gave birth to at least one child. This study included 24 women (22.42%) who had given birth once and presented with an ovarian mass. Additionally, there were 16 women (14.97%) who had given birth four or more times. This elucidates the inverse relationship between low parity and increased susceptibility to ovarian masses in comparison to high parity. Similar findings were discovered in the study conducted by Jyothi Shetty et al (2019)[18] and in the studies conducted by Soo Young Jeonget al (2020) [17]. According to a study conducted by Kezia Gaitskell in 2017, women who have given birth have a 26% reduced risk of developing ovarian cancer compared to women who have not given birth. The risk of ovarian cancer was significantly reduced, particularly after the first birth, with a nearly 20% decrease in risk compared to women who have never given birth. This study aims to assess specific risk factors, 92 women (85.99%) had body mass index (BMI) of 30kg/m² or less. Conversely, 15 women (14.01%) had BMI greater than 30kg/m². Soo Young Jeong et al. (2020) discovered that 22.4% of

women had a BMI greater than 30kg/m². An association has been observed between obesity (BMI > 30kg/m²) and an increased likelihood of developing ovarian masses. In current study, 5 women (4.67%) reported having a family history of ovarian cancer. Two women, accounting for 1.86% of the total, reported a family history of breast cancer. Chen H et al (2019)[57], Soo Young Jeong et al (2020)[17], and Shetty J et al (2019)[18] have also reported instances of breast and ovarian cancer occurring in individuals with a positive family history. This signifies those cancers, which runs in families have inherited genetic mutations that increases the risk of ovarian cancer. Furthermore, there is a hereditary predisposition to ovarian cancer. The current study found a notable distinction in serum CA125 levels between benign and malignant lesions (p=0.021). Moreover, a notable disparity was observed in the aforementioned two studies. Patients with malignant ovarian masses exhibit significantly elevated serum CA125 levels compared to those with benign masses. The results of our study showed that malignant lesions had a significantly larger diameter compared to benign lesions. Additionally, the proportion of solid tissue was significantly higher in malignant lesions (p<0.001), and there were significantly more papillae larger than 3 in malignant cases (p=0.023). Comparable findings were identified in the study conducted by Chen H et al [16] and the study conducted by Soo Young Jeong et al [17]. The results of our study did not reveal any statistically significant disparity in terms of acoustic shadows and ascites. However, there was a significant increase in the presence of locules greater than 10 in malignant cases compared to benign cases. In the studies conducted by Chen H et al [16] and Soo Young Jeong et al [17], it was found that the proportion of patients with ascites and locules exceeding 10 was notably greater in patients with malignant ovarian masses. IOTA reported 81 women (75.70%) as benign ovarian lesion and 26 (24.30%) as malignant. Butureanu T et al [19] found that by using the IOTA ADNEX model, the study detected that the rate of benign tumor masses was 91.8–99.7%, the rate of borderline tumors represented 0.3–4.5% and the rate of malignant tumors was 0.3–8.2%.

Nohuz E et al found that the IOTA score classified 74 lesions as benign lesions (79.6%), 2 as malignant lesions (2.1%) and 17 unable to be classified (18.3%). [16] The majority of patients in our study underwent Unilateral Salpingo-oophorectomy with comprehensive surgical staging (47.67%), followed by Total Abdominal Hysterectomy with Bilateral Salpingo-oophorectomy with comprehensive surgical staging (36.44%). Only 3 patients (2.80%) underwent Debulking and chemotherapy. The most prevalent benign ovarian tumour identified in the current study was Papillary Serous Cyst adenoma, accounting for 22.42% of cases. The most prevalent borderline tumour observed was the Borderline

Mucinous Tumour, accounting for 2.80% of cases. The predominant malignant ovarian tumour identified in the current study was Papillary Serous Adenocarcinoma, accounting for 14.01% of cases, followed by Mucinous adenocarcinoma, which accounted for 4.67%. The histopathological report of the current study revealed that out of 107 patients, 75 (70.09%) were diagnosed with benign ovarian lesions, while 32 (29.91%) were found to have malignant lesions. The study compared the results of IOTA and HPR, and discovered that out of 75 cases that were determined to be benign, IOTA correctly identified 74 as benign and classified 1 as malignant. Out of the 32 cases that were diagnosed as malignant by HPR, IOTA correctly identified 25 as malignant and identified 7 as benign. The association was determined to be statistically significant with a p-value of 0.001.

In a study conducted by Tudor Butureanu et al. (2021), the IOTA ADNEX model was used to determine the rates of different types of tumours. The study found that the rate of benign tumour masses ranged from 91.8% to 99.7%, the rate of borderline tumours ranged from 0.3% to 4.5%, and the rate of malignant tumours ranged from 0.3% to 8.2%. However, only five cases (2.17%) were found to have histologically confirmed malignant tumours, despite the IOTA ADNEX model indicating a malignant risk of less than 3.9% and a borderline tumour risk of less than 2.4%. The authors achieved a false negative rate of 2.17% for malignancy. The Sensitivity, specificity, Positive predictive value, and Negative predictive value of IOTA, in comparison to histopathology, were determined to be 91.36%, 96.15%, 98.67%, and 78.12%, respectively. The diagnostic accuracy of IOTA, when compared to histopathology, was determined to be 92.52%. The IOTA ADNEX method is a valuable tool for early-stage diagnosis of adnexal masses and for efficiently managing patients in a cost-effective manner. The American College of Obstetricians and Gynaecologists (ACOG) recommends the use of the IOTA ADNEX model to accurately assess the risk of a particular type of adnexal mass. This model can provide improved management options for patients with ovarian tumours. [21]

CONCLUSION

Ovarian cancer is one of the deadliest gynaecological cancers due to its early symptoms and lack of effective screening methods. IOTA (International Ovarian Tumour Analysis) recently developed the multiclass ADNEX (Assessment of Different Neoplasias in the adneXa) model for early ovarian cancer diagnosis and screening. This study found that IOTA ADNEX model can distinguish benign and malignant ovarian masses with high diagnostic accuracy (92.52%), specificity (96.15%), sensitivity (91.36%), and positive predictive value (98.67%). IOTA ADNEX model uses simple clinical

parameters and ultrasonography findings to quickly predict ovarian mass to be benign or malignant, helping clinicians in low-resource settings. This could aid in early planning and systematic ovarian mass management. It classifies ovarian masses as benign and four malignant subtypes (borderline, stage I, stage II-IV, ovarian metastases) to aid preoperative diagnosis of masses and thus effective management of masses will be possible. As correctly classifying the malignancy subtype is critical step because borderline and early-stage ovarian cancer can be treated meticulously and less aggressively. It also helps intriaging the patients for better management and decide whether to have surgery at a general gynecology unit or a cancer center. ADNEX model helps plan laparoscopy or laparotomy for fertility-preserving surgeries in young women or treat the metastatic ovarian cancer based on primaries. Thus IOTA ADNEX model is an appropriate tool for preoperative diagnosis and management of women with ovarian masses.

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