

Title: Reliability of International Ovarian Tumor Analysis (IOTA) models in evaluating ovarian tumors at a tertiary care hospital

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Background

Ovarian cancer is the most aggressive among all gynecological malignancy. The five years survival rate is only 40% and accounting for approximately 50% death due to all gynecological malignancy.^{1,2} The most important prognostic factor is stage at the time of diagnosis.³

A standardized technique “simple rules” for preoperative classification of ovarian tumors was defined by IOTA groups. It provides consistency in defining morphological features of ovarian tumour. It was published by Timmerman in 2008 and validated by several other studies.⁴⁻⁷ Major highlight of the study were 10 simple ultrasound rules. On application of one or more M-rules in the absence of a B-rule, or one or more B-rules in the absence of a M-rule, the mass is classified as malignant or benign respectively. If both M-rules and B-rules apply, or if no rule applies, the mass could not be classified.⁸

The ADNEX (Assessment of Different Neoplasia in the Adnexa) predict the risk that an ovarian mass is benign, borderline or malignant.it includes total nine parameters: in which three are clinical parameters and six are ultrasound parameters. The risk of malignancy is calculated by online algorithm <http://www.iotagroup.org/adnexmodel/site%20iota.html>. Knowledge of the specific type of ovarian pathology before surgery is likely to improve patient triage with high accuracy, and it also help in optimizing the treatment.

In various studies published previously the IOTA ultrasound rules were not applied directly during sonographic examination of patient, the available sonographic data was collected and evaluated as per prediction models retrospectively. This study aimed to test reliability of these risk prediction models in discriminating benign and malignant cyst.

MATERIALS AND METHODS

The study was prospective cohort study carried out in the Department of Obstetrics & Gynecology at AIIMS, BBSR from august 2019 to august 2020 after Institute Ethics Committee approval. Mandatory written informed consent was taken from all the patient for participation in this study. Patient with suspicion of ovarian tumour on pelvic examination or discovered during previous sonographic examination were included and pregnant patient, patient not willing for participation in the study and not underwent surgery at our institute were excluded from this study. All participants underwent standardized ultrasound examination as per IOTA rules and also risk stratification by IOTA ADNEX model before surgery. Results of both IOTA simple rules and ADNEX model were compare with histopathological diagnosis. The staging of malignant tumours was done as per FIGO classification. The diagnostic accuracy of IOTA simple rules was estimated by calculating sensitivity, specificity, positive predictive value, accuracy taking histopathological study as the gold standard.

Result:

During the study total 52 patient with ovarian tumours reported at our institute. Two of them were excluded because of pregnancy. Total 50 patients were included in this study.

The youngest patient in the study was 16 and the eldest was 53 years old.

Most patient were in age group 41-50 years.

Out of 50 patients, 6 patients had bilateral tumours, larger one was considered for the study.

Out of total 50 cases studied; IOTA simple rules were applicable on 48 cases. As per IOTA simple rules 43 were benign tumours, 5 were malignant and 2 were indeterminate.

Considering indeterminate tumour as malignant tumours total malignant lesions came to be 7.

For detection of malignancy by IOTA simple rules the sensitivity was - 83.3 %, specificity - 95.45 %, PPV-71.4%, NPV-97.6% and accuracy was 94%. On applying ADNEX model on five histopathological proven malignancy, three were correctly classified into their stages.

Age groups (yrs)	Benign	Malignant
	No	No
11-20	02	0
21-30	10	0
31-40	10	2
41-50	18	1
51-60	5	2

Menopausal status	Benign	Malignant
Postmenopausal	08	02
Premenopausal	37	03
Total	45	05

Sensitivity	83.3
Specificity	95.5
PPV	71.4
NPV	97.6
Accuracy	94

Nature of the mass as per IOTA Rules	No.	Histopathological result	
		Benign	Malignant
Benign	43	42	01
Malignant	07	02	05

Histopathology	Benign (%)	Malignant (%)
Syn Adenocarcinoma grade 1 neuroendocrine tumour in mature teratoma	99.3	0.7
Mucinous cyst adeno ca	81.9	18.1
Mucinous cyst adeno ca	34.7	65.3
Granulosa cell tumour	35	65
serous cystadenocarcinoma	21.6	78.4

Discussion:

In previous published studies (mentioned in table 6), the sonographic data was collected retrospectively from patients and was evaluated as per prediction models. The major strength of our study is that IOTA simple ultrasound rules were applied directly on the patients. The sensitivity and specificity of present study most closely related to study by Sayasneh A et al., who reported a sensitivity and specificity of 87% and 98% respectively. The sensitivity of our study was lower as compared to various retrospective studies. This variation may be due to limited number of patients studied in the present study as compared to other studies.

Author with year	No. of patient	Malignant	Benign	sensitivity	specificity
Timmerman D et al., (2008)	507	-	-	95	91
Timmerman D et al., (2010)	1938	542	1396	92	96
Fathallah K et al., (2011)	122	14	108	73	97
Hartman CA et al. (2012)	103	30	73	91	87
Sayasneh A et al., (2013)	255	74	181	87	96
Alcazar JL et al., (2013)	340	55	285	88	97
Nunes N et al., (2012)	303	135	168	96	89
Present study	50	05	45	83.3	95.45

Limitation: The major limitation of this study was small sample size. The study did not achieve its desired sample size (i.e. 90) because of suspension of elective procedures in amidst COVID-19 pandemic at our institute.

Conclusion: The sensitivity for the detection of malignancy was 83.3 % and the specificity was 95.45%. Accuracy was 94%. The time of diagnosis being the most important prognostic factor in ovarian malignancy. Hence, early and correct diagnosis improve the survival rate. USG offers inherent advantages of easy availability, affordability and lack of radiation exposure but major disadvantages being more subjective than other modalities. IOTA simple ultrasound rules can eliminate this problem as they are highly sensitive and specific in predicting ovarian malignancy preoperatively by providing consistency in describing morphology of these lesion. These standardized terms and rules are reproducible, easy to learn and practice.

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