

DOI: <https://dx.doi.org/10.18203/2320-1770.ijrcog20231922>

Original Research Article

Validity of international ovarian tumour analysis simple rules in characterization of ovarian mass

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Received: 26 April 2023

Accepted: 01 June 2023

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ABSTRACT

Background: Ovarian malignancy is one of the most common cancer in women and is diagnosed at later stage in majority. The limiting factor for early diagnosis is lack of standardized terms and procedures in gynaecological sonography. Recently, IOTA simple rules have been externally validated to have an increased sensitivity and specificity in diagnosing ovarian malignancy.

Methods: This is a prospective study in the Department of obstetrics and gynaecology conducted at ESIC-MC & PGIMSR Hospital, Bangalore from January 2020 to June 2021. 50 women diagnosed with ovarian mass and scheduled for surgery were admitted and evaluated for nature of ovarian mass using IOTA simple rules on ultrasonography and correlated with their histopathological diagnosis.

Results: Among 50 ovarian masses, all 38 masses (76%) characterized as benign by IOTA simple rules were true benign (100%) on histopathological diagnosis. 10 masses (20%) characterized as malignant, 9 were true malignant and 1 was false malignant on histopathological diagnosis. 2 cases which were inconclusive by IOTA simple rules were characterized as benign on histopathological diagnosis. Thus in our study test sensitivity was 100%, specificity 97.56%, positive predictive value 90% and negative predictive value 100%.

Conclusions: In clinical practice, IOTA simple rules as a diagnostic tool helps in characterization of most ovarian masses, which aids in optimal management and enhance better outcome. In ovarian masses for which the rules yielded an inconclusive results, subjective assessment by an experienced sonologist is advocated.

Keywords: Histopathological examination, IOTA'S simple rules, Ovarian tumour

INTRODUCTION

Ovarian malignancy constitutes about 15-20% of genital malignancy.¹ It has highest case fatality ratio, hence early diagnosis is most important factor for better prognosis.²

Pre operative knowledge regarding the nature of ovarian mass is important for plan of management since they need different interventions. Sonographic evaluation has been largely used for predicting the nature of the adnexal mass. Both transabdominal and transvaginal techniques along

with doppler examination provides optimal visualisation of ovarian mass and this has eliminated unnecessary surgery in patients who can be managed medically.³⁻⁶ The best method for discrimination between benign and malignant adnexal mass is the subjective assessment of ultrasound findings by an experienced sonologist. However, such expert knowledge is not available in every centre.⁷⁻⁸

The International ovarian tumour analysis (IOTA) group proposed simple ultrasound based rules for diagnosis of

ovarian malignancy, based on morphologic findings of adnexal mass and colour doppler, 5 ultrasound features suggestive of benign lesions (B features) and 5 ultrasound features suggestive of malignancy (M features).⁹

The present study was designed to assess the diagnostic ability of IOTA'S simple rules in discriminating ovarian mass as benign or malignant compared with histopathological diagnosis as gold standard.

METHODS

This prospective cross sectional study was conducted in the department of obstetrics and gynaecology– ESIC-MC and PGIMS, Rajajinagar, Bangalore – 10, from January 2020 to June 2021 (18 months). After the approval of the protocol from Institutional Ethical Committee, 50 women diagnosed with ovarian mass and scheduled for surgery were enrolled for the study.

According to the previous literature the proportion of malignant tumours among ovarian mass is found to be 15% and sample size is calculated with power = 80%, relative precision of 10% and α of 0.05. The sample size is found to be 50 using openepi.com.

Inclusion criteria

Women aged 18 years and above with ovarian mass who required surgery and women who gave informed written consent for the study were included.

Exclusion criteria

Women with benign functional ovarian mass for conservative management and pregnant women with ovarian mass were excluded.

Method of collection of data

50 women diagnosed to have ovarian mass meeting the inclusion criteria were clinically evaluated with detailed clinical history, general physical examination, systemic examination and all women underwent ultrasound examination either transabdominal or transvaginal approach as suitable. Based on simple rules of IOTA, morphological features and colour flow mapping, the mass is differentiated as benign or malignant tumour accordingly. Colour doppler appearance on TAS/TVS were categorized as follows score 1-no blood flow, score 2-mild blood flow, score 3-moderate blood flow, score 4-high/very high blood flow.

If one or more B- features were present in the absence of M- features, the mass was classified as benign. If one or more M-features were present in the absence of B-features, the mass was classified as malignant. If both B and M features were present or none were present, the mass was classified as inconclusive.

After preoperative evaluation of the mass, women underwent planned surgery and the surgical specimen sent for histopathological diagnosis which is the gold standard in our study. All the data were documented in the pretested proforma.

RESULTS

There were 50 women with ovarian mass were assessed using IOTA'S Simple rules either by transabdomen or transvaginal sonography. A comprehensive case history, clinical examination, preliminary clinical diagnosis, and histological diagnosis were all documented. The following observations and outcomes were recorded.

Table 1: Age-wise distribution of study cases.

Age (yrs)	Subjects N= 50	Percentage (%)
25-34	06	12
35-44	20	40
45-54	13	26
55-64	09	18
≥ 65	02	4
Total	50	100

Majority of the patients were in the age group of 35 to 44 years (40.0%), followed by 45 to 54 years (26%). The youngest patient aged 28 yr and the oldest 66 yr. The mean age group was 44 years (Table 1).

Table 2: Distribution of IOTA'S simple rules result among the study cases.

Type	Subjects N=50	Percentage (%)
Benign	38	76
Malignant	10	20
Inconclusive	02	4
Total	50	100

Table 3: Distribution of IOTA-simple rule benign features among the study cases.

Simple rules B - features	Subjects n = 38	Percentage (%)
B1+B2	01	2.6
B1+B4	06	15.7
B1+B5	06	15.7
B2	01	2.6
B2+B4	02	5.2
B2+B5	06	15.7
B3	02	5.2
B3+B2	01	2.6
B3+B4	03	7.8
B3+B5	06	15.7
B4+B3+B5	01	2.6
B4+B5	03	7.8
Total	38	100

Among 50 patients, IOTA'S simple rules diagnosed 76% as benign, 20% as malignant and 4% as inconclusive (Table 2).

Among 38 cases diagnosed as benign ovarian mass, 92% had more than one B- feature and only 8% had single B – feature (Table 3).

Table 4: IOTA-simple rules-malignant (M) features distribution among the study cases.

Simple rules M-features	Subjects n = 10	Percentage (%)
M1+M2+M4	01	10
M1+M2+M5	01	10
M1+M3+M4	02	20
M1+M3+M5	01	10
M1+M4+M5	01	10
M2+M4+M5	02	20
M3	01	10
M4+M1	01	10
Total	10	100

Among 10 cases diagnosed as malignant ovarian mass, 90% had more than one M-feature and only 10% had single M-feature (Table 4).

Distribution of IOTA'S simple rules -inconclusive

Two cases (4%) were inconclusive in our study, both B and M features of IOTA'S Simple rules were absent. On histopathology one case diagnosed to be ovarian fibroma and other case diagnosed to be broad ligament fibroid.

50 ovarian masses based on their colour doppler appearance on TAS/TVS were categorized as score 1-no blood flow [80 % cases (n=40)], score 2-mild blood flow [4% cases (n=2)], score 3-moderate blood flow [8% cases (n=4)], and score 4-high/very high blood flow [8% cases (n=4)] (Table 5).

Table 5: Distribution among the cases based on colour doppler score.

Colour doppler score	Subject N=50	Percentage (%)
Score 1	40	80
Score 2	02	4
Score 3	04	8
Score 4	04	8
Total	50	100

In the present study, total 50 cases of ovarian masses diagnosed on histopathology, 82% cases (n=41) were diagnosed to be benign whereas, 18.0% cases (n=09) were diagnosed to be malignant (Table 6).

Table 6: Distribution of study cases on histopathology diagnosis.

Histopathology diagnosis	Subjects N=50	Percentage (%)
Benign	41	82
Malignant	09	18
Total	50	100

Table 7: Distribution of study cases according to histopathology diagnosis.

Histopathology diagnosis	Subjects N=50	Percentage (%)
Simple serous cyst	07	14
Dermoid cyst	04	8
Endometriotic cyst	04	8
Fibroma ovary	01	2
Follicular cyst	01	2
Haemorrhagic cyst	02	4
Mucinous cystadenoma	12	24
Leiomyoma	01	2
Left hydrosalpinx of fallopian tube	01	2
Serous cystadenofibroma	01	2
Serous cystadenoma	07	14
Mature cystic teratoma with SCC	01	2
Mucinous cystadenocarcinoma	02	4
Immature teratoma	01	2
Papillary serous cystadenocarcinoma	01	2
Serous cystadenocarcinoma	03	6
Clear cell carcinoma	01	2
Total	50	100

The Table 7 depicts various histopathological diagnosis of the surgically excised specimens. Among 50 cases studied, on histopathology 41 were found to be benign and 9 were found to be malignant.

In the Table 8 simple rules results are compared with the histopathological diagnosis. All the 38 benign tumours diagnosed on IOTA'S simple rules are confirmed to be benign on histopathological diagnosis. Among 10 ovarian masses with malignant features by IOTA'S simple rules, 9 were confirmed to be malignant and 1 which was falsely diagnosed to be malignant on IOTA'S simple rules was diagnosed as benign serous cystadenofibroma on histopathological diagnosis and 2 masses which were found to be inconclusive on IOTA'S simple rules was diagnosed as ovarian fibroma and broad ligament fibroid in histopathological diagnosis. This association between the both the test results were statistically significant with P value 0.001 (Table 9).

Table 8: Association between simple rule results and histopathology diagnosis among the study cases.

Histopathology diagnosis N= 50 (%)	Simple rule results N=50 (%)			Total	P value
	Benign features	Malignant features	Inconclusive features		
Benign	38	01	02	41	0.001
Malignant	00	09	00	09	
Total	38	10	02	50	
Chi-square value	43.90				

Table 9: Association between simple rule results and histopathology diagnosis among the study cases.

Histopathology diagnosis N= 50 (%)	Simple rule results N=50 (%)		Total	P value
	Benign	Malignant		
Benign	40 (97.6) (true benign)	01 (02.4) (false malignant)	41(82)	0.001
Malignant	00(00) (false benign)	09 (100) (true malignant)	09 (18)	
Total	40 (80)	10 (20)	50 (100)	
Chi-square value	43.90			

Table 10: Diagnostic accuracy of simple rule results and histopathology diagnosis among the study cases.

Diagnostic accuracy	Percentage
Sensitivity	100
Specificity	97.56
Positive predictive value	90
Negative predictive value	100

DISCUSSION

The ability of the IOTA simple rules to distinguish between benign and malignant ovarian tumours has been prospectively evaluated in this study. The results of this study confirmed that when the simple rules yielded a conclusive result, they reliably discriminated between benign and malignant ovarian masses. In the present study, the mean age among study participants is 44 years. In comparison, Hartman et al in their study found that the mean age was 47 years, whereas Hafeez et al found that the mean age was 41 years in their study.^{10,11} Simple rules were utilised to characterise the ovarian masses either as benign, malignant or inconclusive, which was done to determine the diagnostic performance of IOTA for assigning a specific diagnosis to adnexal masses. The histology of surgically excised adnexal tumours was considered as a reference standard. In our study, the simple rules were applicable in 96% of the cases that is 48 of the 50 ovarian masses. Study by Hartman et al, the IOTA simple rules could be implemented in 82.7 % of 110 adnexal tumours and study by Fathallah et al, simple rules were applicable in 89.3% of 122 masses studied.^{10,12}

In the present study, 4% that is 2 out of 50 cases were inconclusive or unclassifiable. In comparison, Tinnangwattana et al observed that inconclusive results were in 6% of the cases.¹³

Among 50 cases, 20% were diagnosed as malignant, 76% diagnosed as benign and 4% diagnosed as inconclusive by

simple rules of IOTA. In comparison, in a study done by Hartman et al, out of total 103 patients, 23.0% were malignant and 65.04% were diagnosed benign by IOTA'S simple rules and pattern recognition.¹⁰ And another study done by Sokalska et al 2009, out of a total 1066 patients, 25.0% were malignant and 75.04% were benign.¹⁴

In our study, all 40 cases diagnosed benign on IOTA simple rules and pattern recognition were also benign on histopathological diagnosis. Among the 10 cases diagnosed as malignant, 9 were confirmed malignant by histopathological diagnosis and 1 falsely diagnosed malignant tumour was diagnosed as benign serous cystadenofibroma on histopathology. In the present study of 50 patients with ovarian masses, the sensitivity and specificity of IOTA simple rules in comparison with histopathological diagnosis were 100% and 97.56%, respectively. In a study by Shetty et al, the sensitivity and specificity of IOTA (using both approaches -simple rules and pattern recognition) were 92.8 and 92.9 percent, respectively.⁹ In comparison, Hartman et al found that IOTA'S simple rules and pattern recognition had 90% sensitivity and 87 percent specificity in diagnosing benign and malignant tumours, respectively.¹⁰ Another study by Alcazar et al, in their study found that IOTA simple rules had sensitivity of 87.9% and specificity of 97.5%.¹⁵ In the meta analysis comprised of 6 studies done by Nunes et al, pooled sensitivity was 93% and pooled specificity was 95%.¹⁶

In the present study of 50 patients with ovarian masses, the positive predictive value and negative predictive value of IOTA simple rules in comparison with histopathological diagnosis were 90% and 100% respectively. Study by Saima et al found that positive predictive value was 93 percent, and the negative predictive value was 89 percent.¹¹

Simple rules of IOTA helps in characterisation of ovarian mass as malignant or benign which helps in the optimal management of the patient and in those with inconclusive

results subjective assessment by an experienced ultrasound examiner is advocated. In our study, standardized simple IOTA rules were strictly applied to all the 50 cases and appropriately categorized as benign and malignant as per simple rules of IOTA from high resolution images captured by a single experienced radiologist to avoid interobserver variations which led to higher sensitivity and specificity in our study.

Smaller sample size and short duration of the study are the limitation of the present study.

CONCLUSION

The IOTA simple rules offer a great diagnostic performance when it comes to distinguishing between benign and malignant ovarian tumours. When the rules yield an inconclusive finding, they must be referred to an experienced ultrasound examiner for pattern recognition. Simple rules of IOTA in clinical practise offer a quick characterisation of most ovarian masses and has the potential to enhance the outcome in management.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

- Konar H, Dutta DC. Textbook of gynaecology. 6th ed. Jaypee Brothers Medical Publishers(P) LTD;2013:274-323.
- Rao PS, Reenu B, Prajwal S. Risk of malignancy index in ovarian tumour for predicting ovarian malignancy by using Jacob `score. Int J Reprod Contracept ObstetGynaecol. 2017;6(4):1318-25.
- Van Holsbeke C, Daemen A, Yazbek J, Holland TK, Bourne T, Mesens T, et al. Ultrasound experience substantially impacts on diagnostic performance and confidence when adnexal masses are classified using pattern recognition. Gynecol Obstet Invest. 2010;69(3):160-8.
- Valentin L, Jurkovic D, Van Calster B, Testa A, Van Holsbeke C, Bourne T, et al. Adding a single CA 125 measurement to ultrasound imaging performed by an experienced examiner does not improve preoperative discrimination between benign and malignant adnexal masses. Ultrasound Obstet Gynecol. 2009;34(3):345-54.
- Valentin L. Prospective cross-validation of Doppler ultrasound examination and gray-scale ultrasound imaging for discrimination of benign and malignant pelvic masses. Ultrasound Obstet Gynecol. 1999;14(4):273-83.
- Valentin L, Hagen B, Tingulstad S, Eik-Nes S. Comparison of 'pattern recognition' and logistic regression models for discrimination between benign and malignant pelvic masses: a prospective cross validation. Ultrasound Obstet Gynecol. 2001;18(4):357-65.
- Ferrazzi E, Zanetta G , Dordoni D , Berlanda N , Mezzopane R, Lissoni AA. Transvaginal ultrasonographic characterization of ovarian masses: comparison of five scoring systems in a multicentre study. Ultrasound Obstet Gynecol. 1997;10(3):192-7.
- Alcazar JL, Merce LT, Laparte C, Jurado M, Lopez-Garcia G. A new scoring system to differentiate benign from malignant adnexal masses. Am J Obstet Gynecol. 2003;188(3):685-92.
- Shetty J, Saradha A, Pandey D, Bhat R, Kumar P, Bharatnur S. IOTA Simple Ultrasound Rules for Triage of Adnexal mass: Experience from South India. The Jobstetgynecol India. 2019;69(4):356-62.
- Hartman CA, Juliato CRT, Sarian LO, Toledo MC, Jailes RM, Morais SS, et al. Ultrasound criteria and CA-125 as predictive variables of ovarian cancer in women with adnexal tumour. Ultrasound Obstet Gynaecol. 2012;40(3):360-66.
- Hafeez S, Sufian S, Beg M, Hadi Q, Jamil Y, Masroor I. Role of ultrasound in characterization of ovarian masses. Asian Pacific J Cancer Prev. 2013;14(1):603-6.
- Fathallah K, Huchon C, Bats AS, Metzger U, Belda MAL, Bensaid C, et al. External validation of simple ultrasound rules of Timmerman on 122 ovarian tumour. Gynaecol Obstet Fert. 2011;39(9):477-81.
- Tinnangwattana D, Vichak-Ururrote L, Tontivuthikul P, Charoenratana C, Lerthiranwong T, Tongsong T. IOTA simple rules in differentiating between benign and malignant adnexal masses by non-expert examiners. Asian Pac J Cancer Prev. 2015;16(9):3835-8.
- Sokalska A, Timmerman D, Testa AC, Van Holsbeke C, Lissoni AA, Leone FP, et al. Diagnostic accuracy of transvaginal ultrasound examination for assigning a specific diagnosis to adnexal masses. Ultrasound Obstet Gynecol. 2009;34(4):462-70.
- Alcázar JL, Pascual MÁ, Olartecoechea B, Graupera B, Aubá M, Ajossa S ,et al. IOTA simple rules for discriminating between benign and malignant adnexal masses: prospective external validation. Ultrasound Obstet Gynecol. 2013;42(4):467-71.
- Nunes N, Ambler G, Foo X, Naftalin J, Widschwendter M, Jurkovic D. Use of IOTA simple rules for diagnosis of ovarian cancer: meta-analysis. Ultrasound Obstet Gynecol. 2014;44(5):503-14.

Cite this article as: Divya KP, Prabhu S, Prasad SBS. Validity of international ovarian tumour analysis simple rules in characterization of ovarian mass. Int J Reprod Contracept Obstet Gynecol 2023;12:2128-32.