Research Article

Roma Index and Adnex Model: which is more Superior in Predicting Epithelial Ovarian Malignancy?

Index Roma dan Model Adnex: Manakah yang Lebih Unggul dalam Memprediksi Keganasan Ovarium Epitelial?

Feibyg T. Lumandung, Suzanna P. Mongan, Bismarck J. Laihad

Department of Obstetrics and Gynecology
Faculty of Medicine Universitas Sam Ratulangi
Prof. Dr. R. D. Kandou General Central Hospital
Manado

Abstract

Objective: To compare the accuracy of ROMA index and ADNEX model in predicting the risk of malignancy in ovarian tumour.

Methods: This was a prospective analytic study. A total of 37 samples were acquired from women of all ages diagnosed with an ovarian cystic tumour in the Central General Hospital Prof. Dr. R. D. Kandou. A CA-125 marker, HE4 marker, menopausal status and ultrasonography (USG) examination were obtained, and subsequently compared with the final histopathological results. The data were analysed by using the SPSS statistics software.

Results: Thirty-seven women participated in this study. The mean age of participants was 43 years old. The Area Under Curve (AUC) of the ADNEX was 0.979 with a sensitivity of 90.0%, specificity of 88.2%, negative predictive value of 89.8%, and positive predictive value of 80.5%. The AUC of the ROMA model was 0.734 with the sensitivity, specificity, negative predictive value, and positive predictive value of 65.0%, 64.7%, 64.8%, and 64.8%, respectively. Both models showed AUC values > 0.50 (p-value < 0.05).

Conclusions: The IOTA ADNEX had better accuracy than the ROMA model in predicting ovarian epithelial malignancy. The ADNEX model had higher sensitivity and specificity than the ROMA model.

Keywords: ADNEX, CA-125, HE4, Ovarian tumour, ROMA.

Abstrak

Tujuan: *Untuk membandingkan akurasi indeks ROMA dan ADNEX model dalam memprediksi keganasan tumor ovarium*

Metode: *Penelitian ini merupakan studi analitik prospektif. Total 37 sampel penelitian didapatkan dari wanita yang didiagnosa tumor ovarium kistik di RSUP Prof. Dr. R. D. Kandou. CA-125, HE4, status menopause dan pemeriksaan USG dilakukan, dan dibandingkan dengan hasil histopatologi. Data kemudian dianalisa menggunakan program statistik SPSS.*

Hasil: *Tiga puluh tujuh perempuan yang berpartisipasi dalam penelitian ini. Dengan rerata usia 43 tahun. Total Area Under Curve (AUC) dari IOTA ADNEX adalah 0,979 dengan sensitivitas 90,0%, spesifisitas 88,2%, nilai prediksi negatif 89,8%, dan nilai prediksi positif 80,5%. AUC dari model ROMA adalah 0,734 dengan sensitivitas, spesifisitas, nilai prediktif negatif dan nilai predikitif positif 65.0%, 64.7%, 64.8%, dan 64.8% berturut-turut. Kedua model menunjukkan nilai AUC > 0,50 (nilai p <0,05).*

Kesimpulan: *IOTA ADNEX memiliki akurasi yang lebih baik dibandingkan model ROMA dalam memprediksi keganasan ovarium epithelial. ADNEX model memiliki sensitivitas dan spesifisitas lebih tinggi dibandingkan model ROMA*

Kata kunci: *ADNEX, CA-125, HE4, ROMA, Tumor Ovarium.*

Correspondence author. Feibyg T. Lumandung. Department of Obstetrics and Gynecology.
Faculty of Medicine Universitas Sam Ratulangi. Prof.R.D. Kandou General Central Hospital. Manado
Email; lumandungfeibyg@yahoo.com

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INTRODUCTION

Adnexal mass is a mass or tumour originating from the ovarium, fallopian tube, and other structures adjacent to the two organs. Ovarian tumour is considered a major and important adnexal mass. Ovarian tumour is an abnormal growth of mass from the ovarium, which varies from ovarian cyst to ovarian cancer. The prevalence of ovarian cancer is lower than breast cancer, but it is three times more lethal, and the mortality rate caused by ovarian cancer in 2040 is predicted to increase significantly.[1-3] Tumour marker is a vital component of early diagnosis in several types of malignancy. The Carbohydrate Antigen 125 (CA 125) is one of the widely used tumour markers; it increases in some physiological and pathological conditions, such as menstruation, pregnancy, endometriosis, and peritoneal inflammatory disease. However, CA 125 does not increase in approximately 50% of early-stage ovarian cancer cases. Therefore, the specificity of CA 125 is considered to be poor.[4,5]

Another tumour marker has been developed to obtain a better specificity. The Human Epididymis Protein 4 (HEP4) is widely used and investigated in ovarian cancer cases. It is abundantly produced in patients with ovarian cancer. Despite its high specificity, it has poor sensitivity, hence it is not recommended to use HE4 as a single diagnostic modality.[2,5]

In 2014, the International Ovarian Tumor Analysis (IOTA) published The Assessment of Different Neoplasias in the adnexa (ADNEX) model, consisting of three clinical and six ultrasonographic predictors. The ADNEX model was designed to estimate someone's risk of developing benign ovarian tumour, borderline ovarian tumour (BOT), stage I ovarian cancer, stage II-IV ovarian cancer, and metastatic tumour. Some preliminary studies showed excellent prediction performance based on a sensitivity of 96.5% and a specificity of 71.3%. The ADNEX model also can be used to differentiate benign ovarian tumours and ovarian cancer well.[6-8]

Considering the high mortality rate caused by ovarian cancer in Asia, particularly the epithelial one, and the possibility of different accuracy for different populations even by using the same ovarian cancer prediction model, it is essential to conduct a further study to estimate the accuracy of epithelial ovarian cancer prediction models in Asia – especially in Indonesia. Therefore, we conducted a study to analyse the difference in diagnostic accuracy between the ROMA and the ADNEX model in the Central General Hospital Prof. Dr. R. D. Kandou, Manado. This research aimed to compare the accuracy of two diagnostic methods (the ROMA and the ADNEX model) in predicting ovarian cancer preoperatively to histopathological results as the gold standard in ovarian tumour cases.

METHODS

This prospective analytic study aimed to compare the accuracy of two diagnostic methods (the ROMA model and the ADNEX model). This study was conducted from December 2021 until March 2022. The samples were acquired from women of all ages diagnosed with ovarian cystic mass who visited the Department of Obstetrics and Gynecology of Central General Hospital Prof. Dr. R. D. Kandou. Sample size was calculated to represent the whole ovarian tumor population in Central General Hospital Prof. Dr. R. D. Kandou. The samples were obtained as primary data from women of all ages who visited the Department of Obstetrics and Gynecology of Central General Hospital Prof. Dr. R. D. Kandou as outpatients or inpatients with the diagnosis of ovarian cystic mass, met the inclusion and exclusion criteria of the study, and signed the informed consent.

The inclusion criteria in this study were women of all ages who visited the Department of Obstetrics and Gynecology of Central General Hospital Prof. Dr. R. D. Kandou as outpatients or inpatients diagnosed with an ovarian cystic mass from December 2021 until March 2022; have consented to be included in the study and have had histopathology examination carried out as the gold standard in the diagnosis of an ovarian mass. The exclusion criteria were patients who declined to be included in the study and with incomplete data.

The dependent variable in this study was histopathology examination results as the gold standard of adnexal mass diagnosis, and the independent variables were the ROMA model and the ADNEX model. The data were analyzed by using the SPSS statistics software.

RESULTS

There were 37 participants included in this study. Participants ranging from 16 years old to 75 years old. Nineteen of 37 participants has reached menopause, and 14 out of 37 participants

were nulliparous. The mean ages of participants with benign, borderline, and malignant tumours were 43, 55, and 49.5 years old, respectively. Participants' mean Body Mass Index was 25.50 kg/m^2 for benign tumour cases, 34.70 kg/m^2 for borderline tumour cases, and 24.85 kg/m^2 for malignant tumour cases. Ten malignant and one borderline tumour cases presented with more than ten locular cysts. The mean sizes of cysts for benign, borderline, and malignant tumour cases were 14.50 mm, 23.10 mm, and 24.00 mm, respectively. Furthermore, the mean sizes of the solid lesions for each benign, borderline, and malignant tumour case were 11.00 mm, 13.00 mm, and 16.20 mm. The mean laboratory CA 125 levels in benign, borderline, and malignant tumours were 83.09 U/mL, 88.46 U/mL, and 532.4 U/ml, respectively. The mean laboratory HE-4 levels for each benign, borderline, and malignant tumours were 107.86 U/mL, 126.10 U/mL, and 745.67 U/mL.

Table 1. Characteristics Distribution of Study Participants

	Benign		Borderline		Malignant	
	N	**x̄(s)/M(Range)**	**N**	**x̄(s)/M(Range)**	**N**	**x̄(s)/M(Range)**
Age (y o)						
<50	8	29 (16-47)	1	24	10	41.5 (32-49)
≥50	6	53 (51-74)	2	57.5 (55-60)	10	57 (50-75)
Total	14	43 (16-74)	3	55 (24-60)	20	49.5 (32-75)
Number of parity (s)						
0	3	-	1	-	4	-
1	2	-	0	-	4	-
>2	9	-	2	-	12	-
BMI (kg/m²)						
<18.5 (underweight)	0	-	0	-	1	18.0
18.5-24.9 (normoweight)	5	22.2 (20.3-23.6)	1	23.5	9	23.2 (19.0-24.7)
25-29.9 (overweight)	9	26.7 (25.3-29.1)	0	-	8	27.5 (25.0-29.8)
>30 (obese)	0	-	2	42.43 (34.7-50.2)	2	32.3 (31.6-32.9)
Total	14	25.50 (20.30-29.10)	3	34.70 (23.50-50.17)	20	24.85 (18.00-32.90)
Menopausal state						
Premenopausal	8	-	2	-	8	-
Postmenopausal	6	-	1	-	12	-
Diameter of lesion (mm)						
Size of the lesion	14	14.50 (7.60-26.80)	3	23.10 (19.00-31.00)	20	24.00 (12.10-34.40)
Size of the solid lesion	14	11.00 (3.00-23.40)	3	13.00 (11.00-27.00)	18*	16.20 (3.00-26.10)
Number of locules						
<10	14	-	2	-	10	-
>10	0	-	1	-	10	-
Number of papillary projection (s)						
1	5	-	1	-	0	-
2	4	-	0	-	2	-
3	4	-	1	-	6	-
>3	1	-	1	-	12	-
Acoustic Shadow						
Present	11	-	1	-	0	-
Not present	3	-	2	-	20	-
Ascites						
Present	0	-	2	-	20	-
Not present	14	-	1	-	0	-
CA 125						
Levels (U/mL)	14	83.09 (107.60)	3	88.46 (124.74)	20	532.48 (1072.70)
HE-4						
Levels (U/mL)	14	107.86(98.71)	3	126.10(76.60)	20	745.68(1409.84)

*x̄ = mean, s = deviation standard, M = median, *: 2 empty participants' data*

The histopathological examination revealed 20 samples of malignant tumours, 14 samples of benign tumours, and three samples of borderline tumours. Most of the tumour was the mucinous type, consisting of 14 malignant and six benign mucinous tumours.

The comparison of the ADNEX and the ROMA model prediction results were shown in Tables 2 and 3, respectively. The ADNEX showed excellent accuracy in predicting all malignant tumour cases, while the ROMA prediction model failed to predict four cases accurately. The ADNEX accurately predicted 11 out of 14 benign tumour cases, while the ROMA model predicted 6 out of 14 benign ones. The ADNEX predicted three borderline cases correctly, while the ROMA model detected two borderline cases as malignant tumours and one as a benign tumour. The Area Under Curve of ADNEX was 0.979 with a sensitivity of 90.0%, specificity of 88.2%, negative predictive value of 89.8%, and positive predictive value of 80.5%. The AUC of the ROMA model was 0.734 with the sensitivity, specificity, negative predictive value, and positive predictive value of 65.0%, 64.7%, 64.8%, and 64.8%, respectively.

Table 2. The Prediction Results of the IOTA ADNEX Compared to Histopathology Examination Results

		Histopathology Results			
		Malignant	**Benign**	**Borderline**	
IOTA ADNEX	Malignant	20	3	0	
	Benign	0	11	0	
	Borderline	0	0	3	
Total		20	14	3	37

Table 3. The Prediction Results of the ROMA Model Compared to Histopathology Examination Results

		Histopathology Results			
		Malignant	**Benign**	**Borderline**	
ROMA	Malignant	16	8	2	
	Benign	4	6	1	
Total		20	14	3	37

Furthermore, the comparison between the IOTA ADNEX and the ROMA prediction models in detecting malignant tumour cases was analysed in ROC curves by using SPSS analytic software, as shown in Figure 1.

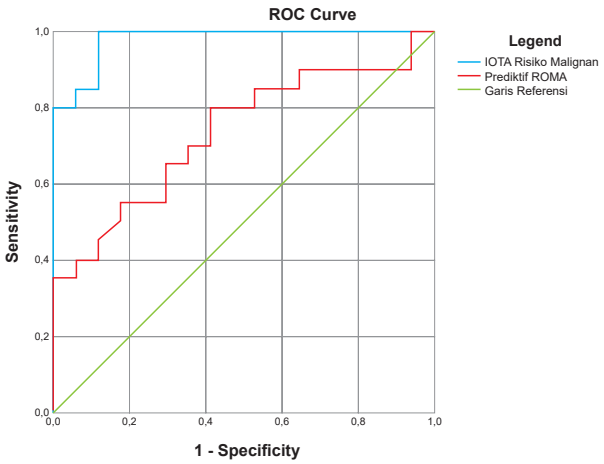

Figure 1. ROC Curves

Table 4. The Prediction Results of the ROMA and IOTA ADNEX Models

	AUC	**CI95%**	**Sensitivity**	**Specificity**	**PPV**	**NPV**	***P-value***
ROMA	0.734	0,572-0,896	65.0	64.7	64.8	64.8	0.015
IOTA ADNEX	0.979	0,944-1,000	90.0	88.2	80.5	89.8	0.000

DISCUSSION

The comparison between the demographic characteristics of the participants, such as age, BMI, parity, and menopausal state, and their respective histopathological results showed less significant value. The age of diagnosis in benign cases was younger than in malignant ones, with an age difference of approximately ten years. This result concluded that old age is a predisposition factor to ovarian cancer incidence. However, our study results showed that participants with borderline cases had older mean age than those with benign and malignant cases. This result was probably due to scarce identification of borderline cases compared to benign and malignant cases, so the data was considered less representative due to a lack of sample numbers.[3]

Parity as a single indicator did not show a significant correlation in the incidence of benign or malignant ovarian tumour cases. This result was in contrast to the results reported that parity had a protective effect on the incidence of ovarian tumours. The difference could be caused by the different sampling techniques used. The study used the case-control method, while our study used the convenience sampling technique in which the samples were obtained from the patients who visited the hospital as outpatients or inpatients.[3,8]

Our study revealed that the subjects with benign cases had greater BMI than that of malignant cases, even though both group were found in the overweight criteria. This finding was similar with previous study that the correlation between obesity based on BMI and the incidence of ovarian cancer was controversial.[3]

The menopausal status in this study demonstrated that more cases of malignant tumours were found in postmenopausal patients compared to premenopausal patients, but it was an insignificant difference. It was in accordance with the result of a study there was a difference between the number of malignant cases in premenopausal and postmenopausal patients by two per cent.[9] It was in contrast to the findings however, the sample in the study was larger compared to our study.[3,10]

The diameter of the lesion tended to increase with the tumour progression into malignant cases. The same result was reported which the mean size of the tumour in stage I cancer is larger than in benign or borderline cases.8 Our study demonstrated a similar result with a ten millimetres difference in tumour mean size between benign and malignant cases.

The more locules in the tumour, the more likely it is to be malignant than benign. A study showed a resembling pattern; a tumour with more than ten locules had a higher probability of being malignant than benign cases.[8]

All subjects in this study had at least one papillary projection. In comparison with another study, the absence of papillary projection was suggestive of a benign case instead of a malignant one. If less papillary projection was present, the tumour would likely to be benign.[8]

The tendency to find an acoustic shadow in ultrasonographic parameters was likely higher in benign cases and less in malignant case. In contrast, the finding of ascites in cases of adnexal masses was more suggestive of malignant tumour conditions. A previous study conducted [11-13] also described the presence of acoustic shadow as a parameter indicating cases of benign tumours and not cases of malignant tumours which could also be found in various types of assessment models, such as the IOTA Simple Rules, IOTA LR, De Priest, and O-RADS. In contrast, the IOTA Simple Rules established the presence of ascites as an indicator parameter for malignant cases.[13,14] Ascites is caused by fluid outflow due to vasodilation which then accumulates in the peritoneal cavity but fails to be reabsorbed into the lymphatic system due to the inhibition of fluid backflow by tumour cells.[15] These findings were then established as excellent additional examination and indicator in predicting the incidence of adnexal tumours, such as ovarian tumours.[14]

The results of the CA 125 and HE 4 parameters in this study showed that an increase could indicate the incidence of malignant tumour cases. This result was in accordance with some studies.[4-5,15] The previous studies also explained that despite the good predictive values of CA 125 and HE 4, they should not be used independently, but rather in combination with other parameters to diagnose malignant ovarian tumours. This resulted in CA 125 and HE 4 being included as parameters in the ROMA Model. [4-5,15,16]

The pathogenesis and pathophysiology of ovarian tumours are multifactorial, so every diagnostic study did not recommend using a single parameter to be considered a causative factor in the incidence of ovarian tumours. This was the background for formulating various ovarian tumour assessment models, such as the

ROMA and IOTA ADNEX models. [4,5,6-7,11,12,15-20]

In the assessment of ovarian tumours, both the ROMA and IOTA ADNEX models demonstrated better accuracy in predicting cases of malignant tumours rather than benign ones.

The comparative study of both prediction models showed that the IOTA ADNEX criteria had higher sensitivity and specificity than the ROMA Model. (90.0% and 88.2% vs. 65.0% and 64.7%). The AUC of the ROMA model was slightly smaller than the IOTA ADNEX model. (0.734; CI95%=0.572-0.896 vs. 0.979; CI95%=0.944-1.000).

The results of the predictive ability of ROMA in estimating the incidence of malignant tumours in this study differed from those, however, it resembled the results with significantly lower sensitivity and specificity than previous studies.[4,15-17,20,22-24] This could be due to the smaller number of study participants, and the comparative analysis between premenopausal and postmenopausal cases was not done. These findings were in accordance with the study which reported that the ROMA criteria had low sensitivity in premenopausal patients.[16]

The predictive performance of the IOTA ADNEX in this study was in accordance with the studies conducted.[7,21,25] This similar result supported the previous studies that the IOTA ADNEX predictive ability is adequately sensitive in detecting cases of malignant tumours despite the small number of study participants.

Some aspects to be reconsidered in the application of the ADNEX or ROMA Model include the facilities of health services available at the time of diagnosis. The ROMA requires CA-125 and HE-4 levels examination. On the contrary, the ADNEX requires a reliable sonographer and laboratory CA-125 level examination to establish the diagnosis,[11] not to mentioned the good accuracy ADNEX possess without CA-125 levels, but the presence of a clinical sonographer remains essential in diagnosing ovarian cancer malignancies using the ADNEX method.[7]

CONCLUSION

The IOTA ADNEX model had better accuracy than the ROMA model in predicting ovarian epithelial malignancy. The ADNEX model had a higher sensitivity and specificity than the ROMA model.

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ETHICAL CLEARANCE

KOMITE ETIK PENELITIAN KESEHATAN
HEALTH RESEARCH ETHICS COMMITTEE
RSUP PROF. DR. R. D. KANDOU MANADO
RSUP PROF. DR. R. D. KANDOU MANADO HOSPITAL

KETERANGAN LAYAK ETIK
DESCRIPTION OF ETHICAL APPROVAL
"ETHICAL APPROVAL"

No.005/EC/KEPK-KANDOU/I/2022

Protokol penelitian yang diusulkan oleh :
The research protocol proposed by

Peneliti utama : Feibyg Theresia Lumandung
Principal In Investigator

Nama Institusi : RSUP Prof dr. R. D. Kandou Manado
Name of the Institution

Dengan judul:
Title

"PERBANDINGAN AKURASI MODEL RISK OF OVARIAN MALIGNANCY ALGORITHM (ROMA) DENGAN ASSESSMENT OF DIFFERENT NEOPLASIAS IN THE ADNEXA (ADNEX) DALAM MEMPREDIKSI KEGANASAN OVARIUM EPITELIAL"

"COMPARISON OF ACCURACY OF THE RISK OF OVARIAN MALIGNANCY ALGORITHM (ROMA) MODEL WITH ASSESSMENT OF DIFFERENT NEOPLASIAS IN THE ADNEXA (ADNEX) IN PREDICTING OVARIAL EPITELIAL MALIGNANCY"

Dinyatakan layak etik sesuai 7 (tujuh) Standar WHO 2011, yaitu 1) Nilai Sosial, 2) Nilai Ilmiah, 3) Pemerataan Beban dan Manfaat, 4) Risiko, 5) Bujukan/Eksploitasi, 6) Kerahasiaan dan Privacy, dan 7) Persetujuan Setelah Penjelasan, yang merujuk pada Pedoman CIOMS 2016. Hal ini seperti yang ditunjukkan oleh terpenuhinya indikator setiap standar.

Declared to be ethically appropriate in accordance to 7 (seven) WHO 2011 Standards, 1) Social Values, 2) Scientific Values, 3) Equitable Assessment and Benefits, 4) Risks, 5) Persuasion/Exploitation, 6) Confidentiality and Privacy, and 7) Informed Concent, referring to the 2016 CIOMS Guidelines. This is as indicated by the fulfillment of the indicators of each standard.

Pernyataan Laik Etik ini berlaku selama kurun waktu tanggal 14 Januari 2022 sampai dengan tanggal 14 Januari 2023.

This declaration of ethics applies during the period January 14, 2022 until January 14, 2023.

Prof. Dr. dr. Max F. J. Mantik, Sp.A(K)