A Model for Malignancy Probability Prediction of Adnexal Masses

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Abstract

Objective : To develop a model for pre-operative malignancy probability determination in a patient with an adnexal tumor or tumors by the application of multivariate logistic regression analysis to variables at the time of pelvic sonography.

Method : Pre-operative ultrasound examination including Doppler analysis was performed on 117 consecutive women scheduled for surgery because of an adnexal mass or masses. Each tumor was classified as probably benign or malignant using a subjective evaluation system on the gray-scale morphological images. Then, Doppler sonography was carried out. The resistance index (RI) and pulsatility index (PI) of the vessel with the highest velocity were recorded.

Multivariate logistic regression analysis was performed with the histological outcome as the dependent variable. Independent variables included patient's age, menopausal status, gray-scale morphological data, RI and PI. The probability of malignancy was formulated from statistical analysis.

Results : There were 117 women included in the study, 83 (71%) with histologically benign and 34 (29%) with histologically malignant ovarian tumors. Regression analysis on the five variables resulted in the retention of only patient's age, morphological data and RI as significant contributing factors for malignancy prediction. The probability of malignancy was $1/(1+e^{-z})$ where e was the base value for natural logarithms and z was the regression equation: - 3.6355 + 1.8028 (age) + 2.1047 (morphological data) + 2.9816 (RI)

Conclusion : A model for estimation of probability of malignancy for an adnexal tumor was derived using multivariate logistic regression analysis. The prediction should be more accurate than that from either gray-scale ultrasound imaging or Doppler velocimetry alone. The test of the model is now on-going.

Key word : Adnexal Mass, Gray-Scale Ultrasonography, Color Doppler Ultrasonography, Flow Indices

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Ovarian carcinoma is a major lethal gynecologic neoplasm in Thailand due to its late presentation. Most cases are asymptomatic until their cancer has already reached stage III or IV. Several studies have attempted to screen or diagnose early stage ovarian carcinoma[1-4]. When an adnexal mass is found, it is important to determine whether it is malignant or not. This issue is of considerable relevance in view of increasing interest in conservative management of benign ovarian tumors, as well as in the selection of patients for a less invasive surgical technique. Moreover, to know in advance the nature of the mass is very useful for the gynecologic oncologist to plan a proper operation on the patient.

Ultrasound is one of the methods that gynecologists normally use pre-operatively in the differential diagnosis of adnexal masses. Different ultrasonographic criteria or scoring systems have been suggested to distinguish between benign and malignant ovarian lesions[5-8]. The efficacy of these screening strategies has been hampered by the degree of overlap between malignant- and benign-appearing masses.

Color Doppler sonography has repeatedly been reported as a diagnostic tool for an ovarian tumor since it enables detection of vessels within masses [9-11]. Initial reports were encouraging showing improvement of sensitivity and specificity over the gray-scale morphologic ultrasonography[5,12-14]. However, some investigators have contradictorily shown that Doppler flow studies do not add substantially to the prediction of malignancy using morphologic assessment alone[15-17]. Moreover, later studies have shown a considerable overlapping of several velocimetric resistance indices between malignant and benign tumors, making the use of this technique controversial[15,18-21]. At present, there is no standard cut off values of Doppler indices to clearly indicate a malignant ovarian tumor.

Experienced ultrasonographers using some clinical information and their subjective assessment of ultrasonographic images can differentiate malignant from benign disease in most cases. However, about 10 per cent of masses are extremely difficult to classify[22]. The main advantage of adding Doppler examination to the subjective evaluation of the gray-scale image is an increase in the confidence with which a correct diagnosis is made[23].

In the present study, the authors aimed to formulate a model for ovarian malignancy prediction using both clinical data and ultrasonographic findings coupled with color Doppler ultrasound.

MATERIAL AND METHOD

A total of 117 consecutive women scheduled for laparotomy or laparoscopic surgery due to a pelvic mass judged clinically to be of adnexal origin were

recruited for the study. An ultrasound examination was performed within 7 days preceding the operative procedure. All examinations were carried out in a systematic and predetermined manner. Each started with a transabdominal and/or transvaginal real-time ultrasound examination of the pelvis. Transvaginal examination was carried out with the woman in the lithotomy position after emptying the bladder. The longitudinal, anteroposterior and transverse diameters of each tumor were measured in centimeters by means of calipers on the frozen ultrasound image. On the basis of subjective evaluation of the gray-scale ultrasound morphology, each tumor mass was classified as benign or malignant according to Reles et al(5). The examiner then immediately carried out Doppler study of this pelvic mass. Tumor vascularization was visualized with the color Doppler technique. The examiner identified the tumor artery with the highest blood flow velocity. Blood flow velocity waveforms were obtained. Arterial Doppler spectra were analyzed from three uniform consecutive heart beats using the built-in software of the ultrasound system. The resulting values of resistance index (RI) and pulsatility index (PI) were averaged and recorded.

Post-operatively, the result of the ultrasound examination was compared with the histological examination of the respective specimen. The tumors were classified in accordance with the system recommended by the World Health Organization(24).

Statistical analysis

A database was established using Microsoft Excel for Windows, which was programmed to facilitate data entry and retrieval. Statistical calculations including multivariate logistic regression analysis were carried out using the software package SPSS for Windows (Version 10.0) (SPSS Inc., Chicago, IL, USA).

Descriptive statistics were used to describe the characteristics of patients enrolled and those of ovarian tumors including ultrasonographic and Doppler findings. The statistics used included mean, standard deviation, number and percentage. The predicting variables for malignant ovarian tumors were age, menopausal status, ultrasonographic morphologic findings, pulsatility and resistance indices. All these factors were characterized and coded as shown in Table 1.

The probability of malignancy was calculated for each predicting factor. Relative risks and their 95 per cent confidence intervals were estimated. Stepwise multiple logistic regression analysis was performed to determine the best predicting formula for malignant ovarian tumor. Removal of variables was determined by the changes in likelihood ratio during the procedure.

RESULTS

Of the 117 women included, the mean age was 41.6 ± 14.2 years. Fifty-six cases (47.9%) were nulliparous, and 30 cases (25.6%) were postmenopausal. Overall, mean RI and mean PI were 1.39 ± 0.69 and 0.65 ± 0.16 respectively.

Pathology of adnexal mass(es) of all the women is shown in Table 2. Seventy per cent of the cases were benign. Histologic cell type was common epithelium in two-thirds of the total cases and the second most common was germ cell tumor.

Association between each predicting factor and malignant lesion was evaluated, as shown in Table 3. The authors found that every predicting factor significantly increased the likelihood of malignancy of adnexal lesion. The probability of malignant lesion was approximately 3.5 times if the patient was ≥ 45 years old or postmenopause (RR 3.47, 95% CI 1.88-6.41; and 3.67, 95% CI 2.15-6.27, respectively). Those with low flow indices were approximately 6.5 times more likely to have malignant lesions (RR 6.49, 95% CI 3.55-11.88 for RI, and 6.55, 95% CI 2.75-15.62 for PI respectively). Ultrasonographic morphology suspicious of malignant lesion showed the strongest

Table 1. Coding of the variables of interest.

	Coding	
	0	1
Patient age	< 45 years	≥ 45 years
Menopausal status	Premenopausal	Postmenopausal
Subjective evaluation from gray-scale ultrasound morphology	Benign	Malignant
Resistance index (RI)	> 0.5	≤ 0.5
Pulsatility index (PI)	> 1.0	≤ 1.0

association (RR 15.0, 95% CI 5.69-39.57).

Stepwise multivariate logistic regression analysis of the data set using all five parameters showed that only patient's age, ultrasound morphological data and RI ≤ 0.5 satisfied the criteria to be included in the equation.

The following equation gave the model of best fit:

$z = -3.6355 + 1.8028$ (age) + 2.1047 (morphological data) + 2.9816 (RI)

Using this model, the probability of malignancy of a given adnexal mass can be estimated by applying the following formula:

$P = 1/(1 + e^{-z})$

P = probability of malignancy

e = the base value for natural logarithms

z = linear formula developed from the logistic regression analysis

For example, a patient who is ≥ 45 years old, with an ultrasonographic morphology suspicious of malig-nant lesion and with RI ≤ 0.5 would have a z value of the following equation:

$z = -3.6355 + 1.8028\ (1) + 2.1047\ (1) + 2.9816\ (1)$

$= 3.2536$

which would give the value of probability $1/(1+e^{-3.2536}) = 0.9628$ or 96.28 per cent chance of malignancy.

Table 2. Final histopathological diagnosis of 117 patients.

	N	%
Tumor potential		
Benign	83	70.9
Malignant	34	29.1
Histologic cell type		
Common epithelium	78	66.7
Germ cell	23	19.7
Stromal cell	4	3.4
Others	12	10.3

DISCUSSION

The standard measure for distinguishing benign from malignant ovarian tumors is histopathologic examination of tissue obtained surgically. An accurate pre-operative diagnosis engenders better pre-operative and intra-operative management and morbidity and even the mortality of these patients may be reduced.

In clinical practice, the basic cornerstones for pre-operative discriminating benign from malignant ovarian tumors are clinical history, pelvic examination, serum tumor markers such as CA-125, pelvic ultrasonography, computed tomography, and magnetic resonance imaging in some cases. Pelvic examination alone has been shown to be of limited value, depending on the clinician's experience. Serum CA-125 level has been suggested as a means to use pre-operatively for prediction of ovarian cancer although its level is elevated in only about half of the patients with early ovarian cancer[25]. This level has been shown to be useful in postmenopausal patients, but its value is considered limited in the premenopausal state, for example it can be elevated in some benign conditions such as endometriosis, pelvic inflammatory disease, or even during menstruation.

Ultrasonography has been widely used to evaluate adnexal masses. Transabdominal ultrasonography was initially used for the detection of early ovarian cancer in asymptomatic women where it was found to be beneficial[26]. Later, the resolving power of pelvic ultrasonography was increased substantially by the advent of transvaginal probes. At present, transvaginal sonography plays an important role in the pre-operative diagnosis of adnexal masses. However, the accuracy of this technique alone is still limited by the fact that a significant number of false positive and false negative results are produced. Initial efforts to distinguish malignant from benign lesions were based on the morphological assessment of tumors by criteria such as the presence or absence of septa or papillary projections, the mass being uni- or multilocular, and the density of the content in the mass[27].

The lack of standardized terms and procedures to derive categorical and variables in gynecological sonography is a general cause of concern[28]. A few years ago, the International Ovarian Tumor Analysis (IOTA) group tried to formulate terms and procedures to derive morphologic end-points by B-mode imaging[29]. Simple morphological classifi-

Table 3. Relative risk of each predicting factor of interest.

Predicting factors (N)	Malignancy	%	Relative risk (95% CI)
Age			
< 45 (73)	11	15.1	1.0
≥ 45 (44)	23	52.3	3.47 (1.88-6.41)
Menopausal status			
Premenopause (87)	15	17.2	1.0
Postmenopause (30)	19	63.3	3.67 (2.15-6.27)
Ultrasonographic morphology			
Benign (78)	4	5.1	1.0
Malignant (39)	30	76.9	15.0 (5.69-39.57)
RI			
> 0.5 (79)	10	12.7	1.0
≤ 0.5 (28)	23	82.1	6.49 (3.55-11.88)
PI			
> 1.0 (55)	5	9.1	1.0
≤ 1.0 (47)	28	59.6	6.55 (2.75-15.62)

cations have been found to be of limited value and a number of scoring systems have been introduced by several groups[6-8]. Recently, there has been an interest in developing scoring systems based on semi-quantitative parameters of the appearance of the tumor. However, difficulties in interpretation still remain. In addition, despite the availability of several scoring systems, most sonographers base their diagnosis on a subjective assessment of adnexal masses by using ultrasonography and the available information including a medical history rather than on the use of scoring systems.

It is known that a malignant tumor needs vascularization to facilitate its rapid growth and angiogenesis is actively operating. In such a process, new capillary vessels develop by sprouting from small vessels or other capillaries. This process, which leads to neovascularization, is initiated by tumor angiogenic factors. The new tumor blood vessels that grow as a result of angiogenesis differ from the normal vasculature of mature tissues with respect to cellular composition, basement membrane structure and permeability[30]. If angiogenesis is regarded as a neoplastic marker for a tumor, then early diagnosis of cancer would be made possible by neovascularization detection. The introduction of transvaginal color and pulsed Doppler ultrasonography has allowed the assessment of adnexal tumor vascularity[31,32]. The arteriolar vascular beds of malignant ovarian tumors have considerable arteriolar-venous shunting with low impedance and high velocity flow that can be detected by color Doppler ultrasound. However, the usefulness of this method is still controversial[16,33,34]. An increasing number of publications demonstrated a significant overlap in the results and the fact that a large number of benign masses had blood flow features similar to those of malignant lesions. In such a situation, when there is no standardization in the Doppler measurement, the operator's responsibility becomes highly significant. A good basic knowledge of Doppler physics is mandatory. The clinician should keep in mind that Doppler flow imaging gives additional useful clinical information for determining ovarian malignancies. The main advantage of adding Doppler examination to subjective evaluation of the gray-scale images is an increase in the confidence with which a correct diagnosis is made.

The authors have often faced the problem of pre-operative diagnosis of adnexal masses. Different levels in experience and expertise pose difficulties in taking care of some patients with adnexal lesions. This is also the case with the complicated use of Doppler study, including the lack of clear cut off values for Doppler indices. Therefore, in the present study, the authors aimed to develop a model to determine the risk of malignancy in adnexal masses. For simplicity, only the patient's age, menopausal status, morphological sonography and tumor vascularity indices (RI and PI) were used. Multivariate logistic regression analysis was used in the present study as it offers some obvious advantages. Firstly, the histopathology of the adnexal tumors could be correlated to multiple parameters rather than just one. Secondly, during the derivation of the model, there are mecha-

nisms such as the forward stepwise selection of variables which will ensure that the most significant predicting parameters are chosen for the regression equation. As such, menopausal status and PI could be excluded from the authors' formula. Although several models for prediction of adnexal malignancy have been reported[14,21,35-38], this is the first model derived in our institute. Hopefully, it will be a useful tool in assessment of adnexal masses since it has been statistically derived from data of case and non-case subjects. Its validity is being prospectively tested in an on-going project in our department. For the time being, it is being used as preliminary information for counseling the patient and her family about the probability of malignancy in case with an adnexal mass examined by gray-scale and color Doppler imaging.

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แบบทำนายโอกาสการเป็นเนื้อร้ายของก้อนที่ปีกมดลูก

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วัตถุประสงค์การวิจัย : เพื่อพัฒนาแบบทำนายโอกาสการเป็นเนื้อร้ายก่อนการผ่าตัด ในผู้ป่วยที่มีก้อนที่ปีกมดลูก โดยใช้การวิเคราะห์เชิงถดถอยหลายตัวแปร กับตัวแปรต่าง ๆ ในขณะทำการตรวจด้วยคลื่นเสียงความถี่สูง

กระบวนการวิจัย : ได้ทำการตรวจคลื่นเสียงความถี่สูง รวมทั้งการตรวจ Doppler ก่อนการผ่าตัด ในผู้ป่วยหญิง 117 รายที่จะเข้ารับการผ่าตัด เนื่องจากก้อนที่ปีกมดลูก ก้อนดังกล่าวได้รับการประเมินว่าน่าจะเป็นเนื้องอกธรรมดา หรือเนื้อร้าย โดยการประเมินลักษณะก้อนจากการตรวจคลื่นเสียงความถี่สูง หลังจากนั้นจะมีการตรวจโดยการใช้ Doppler และบันทึกค่าดัชนีการไหลเวียนเลือด resistance index (RI) และ pulsatility index (PI) ของหลอดเลือดที่มีการไหลเวียนของเลือดที่เร็วที่สุด

ได้ทำการวิเคราะห์เชิงถดถอยหลายตัวแปร โดยมีผลทางพยาธิวิทยา เป็นตัวแปรตาม ส่วนตัวแปรอิสระประกอบด้วย อายุของผู้ป่วย สภาวะว่าอยู่ในวัยหมดระดูหรือไม่ ข้อมูลการประเมินจากการตรวจด้วยคลื่นเสียงความถี่สูง ค่า RI และ PI และสูตรการคำนวณค่าความเป็นไปได้ของการเป็นเนื้อร้ายได้ถูกสร้างขึ้นโดยการวิเคราะห์ทางสถิติ

ผลการวิจัย : มีผู้ป่วย 117 รายในการศึกษานี้ ผลทางพยาธิวิทยา พบว่าเป็นเนื้องอกชนิดธรรมดา 83 ราย (71%) และเป็นเนื้อร้าย 34 ราย (29%) การวิเคราะห์ถดถอย โดยใช้ตัวแปรทั้ง 5 ตัวดังกล่าว พบว่ามีเพียงอายุของผู้ป่วย ข้อมูลการประเมินจากการตรวจด้วยคลื่นเสียงความถี่สูง และค่า RI เท่านั้นที่มีผลต่อการทำนายโอกาสการเป็นเนื้อร้ายอย่างมีนัยสำคัญ โอกาสการเป็นเนื้อร้ายมีค่าเท่ากับ $1/(1+e^{-z})$ โดย e เป็น the base value for natural logarithms และ z มีค่าเท่ากับสมการถดถอย : – 3.6355 + 1.8028 (age) + 2.1047 (morphological data) + 2.9816 (RI)

สรุป : แบบทำนายโอกาสการเป็นเนื้อร้ายของก้อนที่ปีกมดลูก ได้ถูกสร้างขึ้น โดยใช้การวิเคราะห์เชิงถดถอยหลายตัวแปร การทำนายโดยวิธีนี้ควรมีความถูกต้อง มากกว่าการใช้เพียงการประเมินจากการตรวจคลื่นเสียงความถี่สูง หรือ Doppler velocimetry อย่างใดอย่างหนึ่งเพียงอย่างเดียว การทดสอบแบบทำนายนี้กำลังอยู่ในการศึกษาอย่างต่อเนื่องในขณะนี้

คำสำคัญ : ก้อนที่ปีกมดลูก, การตรวจคลื่นเสียงความถี่สูง, การตรวจ Doppler, ดัชนีการไหลเวียนเลือด

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