



Nomogram for the diagnosis of suspected papillary thyroid carcinomas based on sonographic patterns: a retrospective study

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Background: High resolution ultrasonography (US) is the first choice for diagnosis of thyroid cancer and is based on many sonographic features: composition, echogenicity, margins, calcifications, shape and vascularity. Here, we tried to develop a nomogram to evaluate papillary thyroid carcinoma (PTC) based on sonographic features.

Methods: From Aug 2016 to Dec 2017, a primary cohort of 382 patients with suspicious thyroid nodules and accepted US examinations were included in Gansu Provincial Hospital. Sonographic features were used to develop a nomogram with Cox regression analysis. The nomogram was validated using prospective data from 162 patients as the validation group.

Results: The primary and validation cohort showed comparable clinical and US features in all aspects. Univariate and multivariate analyses showed solid composition [odds ratio (OR): 3.785; 95% confidence interval (CI): 1.504–9.528, P=0.005], hypoechoic (OR: 15.840; 95% CI: 5.754–43.602, P<0.001) and irregular margins (OR: 15.953; 95% CI: 5.897–43.160, P<0.001), microcalcifications (OR: 21.730; 95% CI: 7.119–66.329, P<0.001), taller than wide shape (OR: 5.153; 95% CI: 1.997–13.311, P=0.001), internal high vascularization (OR: 6.288; 95% CI: 2.175–18.181, P=0.001), and obscure borders (OR: 5.648; 95% CI: 2.118–15.065, P=0.001) as risk factors for PTC. Based on the seven risk factors, nomogram was developed and validated by a prospective group, and discrimination and calibration were measured using the concordance index (C-index).

Conclusions: Our novel nomogram risk score model based on the US features accurately predicted PTC nodule diagnosis.

Keywords: Papillary thyroid carcinoma (PTC); ultrasonography (US); nomogram

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Introduction

Thyroid nodules are very common and can be diagnosed in up to 67% of people (1). Ultrasonography (US) has been shown to have high sensitivity, specificity, cost-effectiveness, high availability, limited discomfort to patients (2), and an anon-ionizing nature. Up to 10–15% of thyroid nodules are confirmed to be malignant (3). Malignant nodules

require timely surgical treatment, whereas patients with benign nodules can be managed conservatively, so accurate diagnosis of thyroid nodules is vital for treatment (2). However, identification of benign and malignant thyroid nodules is difficult and a consensus identification method had not been reached until now (4). Papillary thyroid carcinoma (PTC) is the most common cell type of thyroid cancer, accounting for up to 85% of all cases (5). Although,

previous study has proved the role of apparent diffusion coefficient value to diagnosis of thyroid cancer (6), high resolution US is still the first choice (7). The sonographic characteristics of thyroid nodules include composition, echogenicity, margins, calcifications, shape, and vascularity (2,7). The pattern of sonographic features associated with a nodule confers malignancy risk and guides fine needle aspiration (FNA) decision making (8).

Although FNA biopsy (FNAB) is still the most reliable test for PTC detection, indeterminate cytology has been observed in up to 30% of FNABs in previous report (9). Meanwhile, this technique is invasive and associated with some complications. Thus, selective nodules suspected of being malignant should be recommended for FNAB, especially for grades 2–5 according to the Thyroid Imaging Reporting and Data System (TI-RADS) (2), in which categories 2 through 5 are divided by the possibility of malignancy. However, the scoring systems are usually too complicated for clinical application (10), meanwhile, it is discontinuous, and hardly give an accurate risk possibility, only provide an interval of malignant risk. The American Thyroid Association (ATA) guidelines provide an estimated risk of malignancy for five sonographic patterns based on the US features. However, the description of the US feature is only a text description with no digital quantification. The purpose of this study was to establish a nomogram to predict the possibility of PTC diagnosis based on the sonographic features of suspicious nodules and guide the application of FNAB.

Methods

Our retrospective study was approved by our hospital's review board and informed consent was obtained from the patients or their families. From Aug 2016 to Dec 2017, Clinical and US data from PTC patients were collected and evaluated at Gansu Provincial Hospital. Five hundred and thirty-two patients were excluded from our study, including 12 due to follicular or medullary thyroid carcinoma, 26 for inadequate sonographic data acquisition, 11 for history of thyroid surgery, 22 for multiple suspicious nodules, and 461 patients for multiple thyroid nodules. A total of 382 patients with solitary nodules were included. All these patients accepted a thyroidectomy, and the diagnosis was confirmed by postoperative histological pathologic examination. According to the pathological examination, the 382 patients were divided into two groups: the PTC group and the benign nodule group. Near-total or total thyroidectomy

as well as lobectomy were performed in all cases. The final diagnosis of the nodules was determined by pathological examination. The baseline characteristics and sonographic features of the two groups were compared.

All patients underwent a thyroid nodule US examination 3 months before surgery. Sonographic features of thyroid nodules were evaluated and scored for composition (solid =2, cystic proportion =1, or spongiform =0), echogenicity (hypoechoic =2, isoechoic=1 or hyperechoic =0), margins (irregular =1 or regular =0), calcifications (microcalcifications with calcifications smaller than 1.0 mm =2, no calcifications =1, macrocalcifications =0), shape (taller than wide =1, no =0), and internal vascularization (high =2, medium =1, low or none =0) according to the ATA guidelines (2). Other characteristics that were recorded and included in our analysis included border type (obscure =1, clear =0), posterior echo (attenuation =1, no attenuation =0), and halo (present =0, absent =1) (11), as well as nodule size (in three dimensions) and location (e.g., left upper lobe). Sonographic examination and evaluation were carried out by two independent sonographic radiologists who were blinded to the pathological outcomes using standard procedures. Both of these observers had at least 5 years of experience in thyroid sonography. In case of disagreement, the two experts worked collaboratively to form a consensus. All sonographic examinations were performed with the patients in a supine position using a color Doppler Philip iE33 ultrasound machine (GELogiq E9, USA) and 6–8 or 10–12 MHz linear probe (ML6-15-D or 9L-D) according to thyroid nodule location. Fine needle aspiration cytology (FNAC) was performed only for patients with suspicious US features. Through a single needle puncture and multiple needle motions under local anesthesia, samples within needles were fixed in 95% ethanol and examined after Papanicolaou staining.

The risk factors for PTC reported in other studies were analyzed in our patients as a primary cohort to develop the nomogram for predicting PTC diagnosis. Then, based on the same selection criteria, we prospectively collected another independent cohort of 162 patients in our hospital that served as the validation cohort.

Continuous variables were expressed as the means \pm standard deviation and compared between the two groups using the *t*-test, and categorical variables were expressed as rates and compared using the chi-square test. Univariate analysis was used to assess the relationship between sonographic parameters and histological diagnosis. Statistically significant variables ($P < 0.05$) were further

analyzed by multiple logistic regression analysis. Univariate and multivariate analyses were performed using the Cox proportional hazards model. The nomogram was built based on the results of multivariate analyses. The final model selection for the nomogram was performed by a backward step-down selection process using the Akaike information criterion (12). Nomograms were generated using the rms package of R software. All other statistical tests were performed with SPSS software (Version 17.0, Chicago, IL, USA). A P value less than 0.05 was considered significant.

Results

As shown in *Table 1*, the primary and validation cohorts included 382 and 162 patients, respectively. Of the 544 included patients, 415 (76.3%) patients had PTC. The baseline clinical and tumor characteristics were broadly similar between the two groups. Meanwhile, preoperative US features were also comparable between the two groups in terms of composition, echogenicity, margins, calcifications, shape, internal vascularization, border, posterior echo, and halo. So, the primary and validation cohorts are comparable.

Based on baseline and US features, PTC patients and those with benign nodules in the primary cohort were compared by univariate analysis. As shown in *Table 2*, although there were gender differences in patients with Hashimoto disease and tumor diameters between the two groups, these differences did not reach statistical significance ($P > 0.05$). According to the US features, PTC patients showed more lesions that were solid, hypoechoic, taller than wide in shape, and with irregular margins, microcalcifications, high internal vascularization, and obscure borders ($P < 0.002$ for all characteristics). However, posterior echo and halo did not show any differences between PTC and benign nodule patients ($P \geq 0.100$).

Multivariate analyses included all variables that are considered significant in the univariate analysis ($P < 0.05$), and each of these seven factors were divided into binary variables. As shown in *Table 3*, the results indicated that all seven factors of US features were the risk factors for PTC and can contribute to the diagnosis of PTC compared to benign nodule US features (all P values were less than 0.01). Receiver operating characteristic (ROC) curve analysis were performed and compared among these seven US features, as showed in *Figure 1*, microcalcification has the largest area under ROC curve, and internal high vascularization has the smallest.

Based on the univariate and multivariate analyses of PTC diagnosis, the seven risk factors based on the US features were incorporated into the PTC diagnosis nomogram, as shown in *Figure 2*. An individual nodule's value is loaded on each variable axis (the 2nd–8th lines) and a line is drawn upwards to determine the number of points received for each variable value (the first line); the sum of these numbers is located on the total point axis (9th line), and a line is drawn downwards to the risk axes (10th line) to determine the likelihood of PTC diagnosis (total point = Composition' score + Echogenicity' + Margins' + Calcifications' + Shape' + Internal Vascularization' + Border', and likelihood of PTC diagnosis can be got according to the total point). In the validation cohort, the baseline characteristics and US features were comparable to the primary cohort. The C-index of the nomogram for predicting PTC diagnosis based on the US features was 0.87 (95% CI: 0.81–0.92), and a calibration curve showed good agreement between prediction and observation (*Figure 3*). These results indicate a high predictive ability of this nomogram.

Discussion

Ultrasonographic-guided FNAB is used to diagnose suspicious nodules for thyroid cancer (2). However, there are some disadvantages, such as inadequate sampling, high cost, invasiveness, indeterminate cytology in some cases, and operator dependency (13,14). Thus, accurate PTC diagnosis using only US is very valuable. The goal of our present study was to establish a nomogram based on US features to precisely diagnose PTC nodules.

The US features for PTCs included in our present study were based on the ATA guidelines (2) and other previous related studies (1,11,14). Previous studies have shown that several US features, such as nodular margins, blood flow distribution, hypoechoic appearance, and microcalcification are associated with PTC malignancy, which was consistent with our multivariate analysis (15,16). We included nine characteristics of US in our research, and, to the best of our knowledge, this is the first study with so many US features for diagnosis of PTC (17,18). However, we did not include sonographic elastography, which is analyzed with related software and probes compared to US (19). The main reason was use of this technique in thyroid nodules applied to only a few patients in our center due to the lack of software.

In our analysis, we included 25 factors that are reported to possibly be related to the risk of PTC (14,20). However, our result detected only US features that can be used to

Table 1 Baseline and US features of nodules

Characteristics	Primary cohort (n=382)	Validation cohort (n=162)	P value
PTC/benign thyroid nodule	295/87	120/42	0.430
Baseline characteristics			
Sex (male/female)	101/281	41/121	0.784
Age (years, mean \pm SD)	40.2 \pm 13.2	40.0 \pm 13.2	0.914
Age (years, \leq 45/45–55/ \geq 55 years)	269/75/38	112/33/17	0.763
BMI (mean \pm SD)	22.4 \pm 4.1	22.1 \pm 4.3	0.553
BMI (\leq 24/ $>$ 24 kg/m ²)	264/118	110/52	0.781
Chronic disease (yes/no)	71/311	31/131	0.994
History of neck radiation (yes/no)	18/364	6/156	0.601
Graves' disease (yes/no)	9/373	1/161	0.101
Hashimoto disease (yes/no)	101/281	37/125	0.363
Nodule largest diameter (mm, mean \pm SD)	14.2 \pm 10.7	15.0 \pm 10.9	0.443
Nodule largest diameter (mm, \leq 10/ $>$ 10)	180/202	70/92	0.403
Location (upper/middle/lower)	183/100/99	76/52/34	0.850
TSH level (mU/L, mean \pm SD)	3.0 \pm 2.6	2.8 \pm 2.2	0.498
FT3 (pmol/L, mean \pm SD)	4.9 \pm 0.8	4.9 \pm 0.7	0.795
FT4 (pmol/L, mean \pm SD)	18.0 \pm 7.3	17.9 \pm 5.8	0.947
US features			
Composition (2/1/0)	276/87/19	116/39/7	0.919
Echogenicity (2/1/0)	266/77/39	98/41/23	0.142
Margins (1/0)	259/123	109/53	0.906
Calcifications (2/1/0)	219/122/41	90/58/14	0.885
Shape (1/0)	212/170	90/72	0.990
Internal vascularization (2/1/0)	176/138/68	74/56/32	0.783
Border (1/0)	208/174	93/69	0.526
Posterior echo (1/0)	89/293	36/126	0.640
Halo (0/1)	73/309	32/130	0.860

Composition (solid =2, cystic proportion =1, or spongiform =0), echogenicity (hypoechoic =2, isoechoic =1 or hyperechoic =0), margins (irregular =1 or regular =0), calcifications (microcalcifications with calcifications smaller than 1.0 mm =2, no =1, macrocalcifications =0), shape (taller than wide =1, no =0), and internal vascularization (high =2, medium =1, low or none =0), border (obscure =1, clear =0), posterior echo (attenuation =1, no attenuation =0), halo (present =0, absent =1). US, ultrasonography; PTC, papillary thyroid carcinoma; BMI, body mass index; SD, standard deviation.

distinguish benign nodules and PTCs. The earliest research on the US features to distinguish benign and malignant thyroid nodes was published by Horvath *et al.* (21). They described ten sonographic patterns of thyroid nodules and the associated risk of malignancy. Similar studies

were subsequently published (22,23); however, it is too difficult to classify each nodule with the entire complex equation. Meanwhile, the categorizing method was too complicated for clinical use, and the suspicious features were assigned the same weight for predicting the nature of a

Table 2 Univariate analysis of diagnosis based on baseline and US characteristics

Variable	PTC patients (n=295)	Benign nodule patients (n=87)	P value
Sex (male/female)	84/211	17/70	0.097
Age (years, $\leq 45/45-55/\geq 55$ years)	203/61/31	66/14/7	0.211
BMI ($\leq 24/>24$ kg/m ²)	201/94	63/24	0.448
Chronic disease (yes/no)	54/241	17/70	0.462
History of neck radiation (yes/no)	14/281	4/83	0.954
Graves' disease (yes/no)	9/286	2/85	0.713
Hashimoto disease (yes/no)	89/206	12/75	0.068
Nodule largest diameter (mm, $\leq 10/>10$)	146/149	34/53	0.088
Location (upper/middle/lower)	142/90/63	41/30/16	0.909
Composition (2/1/0)	235/56/4	41/31/15	<0.001**
Echogenicity (2/1/0)	241/37/17	25/40/22	<0.001**
Margins (1/0)	241/54	18/69	<0.001**
Calcifications (2/1/0)	212/63/20	7/59/21	<0.001**
Shape (1/0)	190/105	22/65	<0.001**
Internal vascularization (2/1/0)	153/91/51	23/47/17	0.001*
Border (1/0)	184/111	24/63	<0.001**
Posterior echo (1/0)	73/222	16/71	0.158
Halo (0/1)	56/239	17/70	0.200

Composition (solid =2, cystic proportion =1, or spongiform =0), echogenicity (hypoechoic =2, isoechoic =1 or hyperechoic =0), margins (irregular =1 or regular =0), calcifications (microcalcifications with calcifications smaller than 1.0mm =2, no =1, macrocalcifications =0), shape (taller than wide =1, no =0), and internal vascularization (high =2, medium =1, low or none =0), border (obscure =1, clear =0), posterior echo (attenuation =1, no attenuation =0), halo (present =0, absent =1). *, P<0.01; **, P<0.001. US, ultrasonography; PTC, papillary thyroid carcinoma; BMI, body mass index.

Table 3 Multivariate analyses of PTC diagnoses based on US features in the primary cohort

Variables	Odds ratio	95% CI	P value
Composition (0–1/2)	3.785	1.504–9.528	0.005*
Echogenicity (0–1/2)	15.840	5.754–43.602	<0.001**
Margins (0/1)	15.953	5.897–43.160	<0.001**
Calcifications (0–1/2)	21.730	7.119–66.329	<0.001**
Shape (0/1)	5.153	1.997–13.311	0.001*
Internal vascularization (0–1/2)	6.288	2.175–18.181	0.001*
Border (0/1)	5.648	2.118–15.065	0.001*

Composition (solid =2, cystic proportion =1, or spongiform =0), echogenicity (hypoechoic =2, isoechoic =1 or hyperechoic =0), margins (irregular =1 or regular =0), calcifications (microcalcifications with calcifications smaller than 1.0mm =2, no =1, macrocalcifications =0), shape (taller than wide =1, no =0), and internal vascularization (high =2, medium =1, low or none =0), border (obscure =1, clear =0). *, P<0.01; **, P<0.001. US, ultrasonography; PTC, papillary thyroid carcinoma; CI, confidence interval.

nodule (2). We established a simple, visual, numeric version of a predictive system based on the US features, which is very important for clinical usage. Xu and colleagues (11) established a scoring and categorizing method based on sonographic features. However, the scoring system was

built based on the odds ratio of multivariate analysis. Risk factor scores were simply added; thus, a precise visual system was not developed in this paper. To the best of our knowledge, this is the first study to establish a nomogram based on US features to diagnose PTCs based on the risk factors of multivariate analysis. Each risk factor is assigned a score, which are summed and represented in the nomogram. The nomogram has been used for various human cancers, such as liver (24), laryngeal (25), lung (26), pancreatic (27), colon (28), and breast cancer (29). The prospective cohort in our hospital was used to validate the effectiveness of this nomogram and obtain a high C-index. We report that the nomogram based on US features was effective to diagnose PTC.

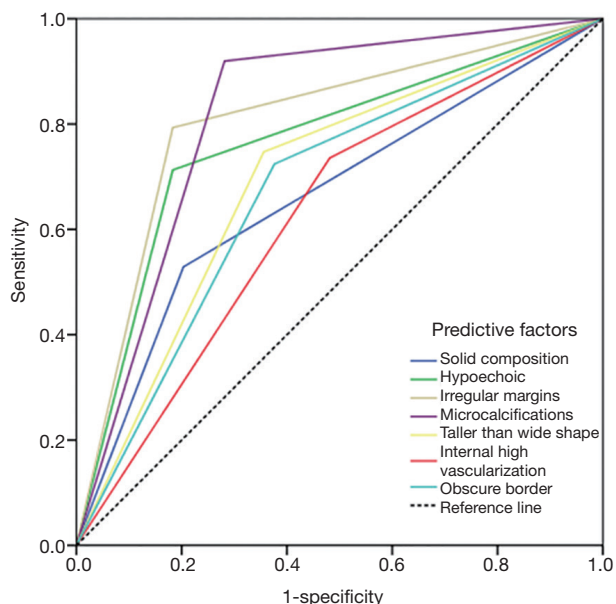


Figure 1 Receiver operating characteristic curve based on the US characteristics to predict PTC diagnosis. US, ultrasonography; PTC, papillary thyroid carcinoma.

Our study does have some limitations. Firstly, there was unavoidable selection bias due to the lack of histological data in ultrasonically small and benign thyroid nodules that have no indication for FNA or surgery. However, long-term follow-up may also demonstrate the benign characteristics. Secondly, the limited patient numbers in a single center may temper our results and conclusions. However, the nomogram was not only built but also validated by a prospective cohort. Furthermore, a multiple center, large cohort study will be performed to further validate the nomogram. Finally, the ultrasonic elastography did not include our present study due to the lack of these data, however, from now on, the ultrasonic elastography will be recommended to suspicious patient, and in our future

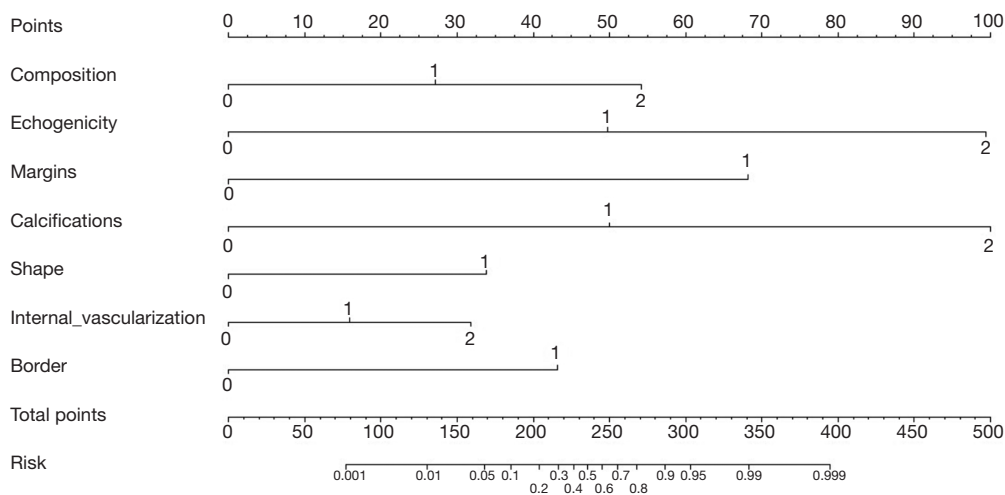


Figure 2 Nomogram for predicting the diagnosis of PTC nodules. To use the nomogram, an individual nodule value is loaded on each variable axis and the line is drawn upwards to determine the number of points; the sum of these numbers is located on the total point axis, and the line is drawn downwards to the risk of a PTC diagnosis. PTC, papillary thyroid carcinoma.

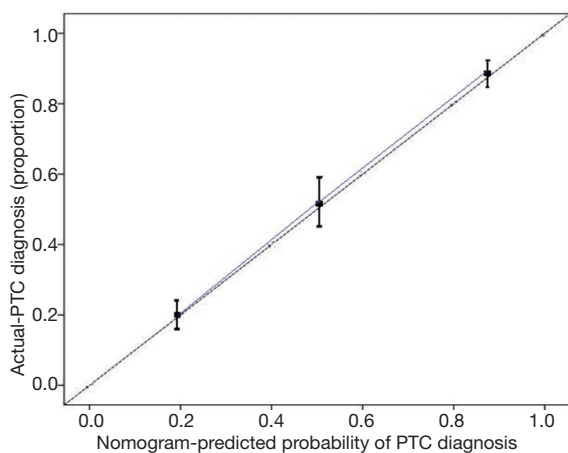


Figure 3 Calibration curves based on nomogram prediction and actual observation in the validation cohort. PTC, papillary thyroid carcinoma.

publication, these data will be present.

In conclusion, we developed a nomogram that could accurately and objectively diagnose PTC nodules based on US features.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Our retrospective study was approved by our hospital's review board (No. 2019-125) and informed consent was obtained from the patients or their families.

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