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Clinical Predictors of Minimal Extrathyroid Invasion of Papillary Thyroid Cancer

Lishchynskyi Pavlo[1], Palamarchuk Volodymyr[1], Mazur Oleh[1], Kuts Volodymyr[2], Zemskov Sergii[3], Tovkai Oleksandr[4], Dronov Olexii[5]

[1] Department of General Surgery №1, Bogomolets National Medical University, researcher of the Department of Endocrine Surgery of Ukrainian Scientific and Practical Center of Endocrine Surgery, Transplantation of Endocrine Organs and Tissues of the MOH of Ukraine, Kyiv, Ukraine

[2] Department of information and computer technologies, National institute of phthisiatry and pulmonology named after F.G. Yanovsky NAMS of Ukraine, Kyiv, Ukraine

[3] Vice-Rector for Research and Innovation, Bogomolets National Medical University, Kyiv, Ukraine

[4] Director of the Ukrainian Scientific and Practical Center of Endocrine Surgery, Transplantation of Endocrine Organs and Tissues of the MOH of Ukraine, Kyiv, Ukraine

[5] Department of General Surgery №1, Bogomolets National Medical University, Kyiv, Ukraine

Address for correspondence:

Lishchynskyi Pavlo

E-mail: endosurg88@ukr.net

Abstract: *extrathyroidal invasion (ETI) of papillary thyroid cancer (PTC) is a risk factor for locoregional metastasis. The clinical significance of minimal ETI depending on the primary tumor size has not been studied thoroughly. The combination of tumor diameter and minimal ETI can be used as a reliable prognostic factor for persistence of the disease. Given that the identification of the minimal ETI is possible only during the final histopathological study, there is a need to assess the existing preoperative clinical predictors that increase the probability of minimal ETI of PTC. The aim of the study is to assess preoperative clinical predictors that increase the probability of minimal extrathyroidal invasion of papillary thyroid cancer. A retro-prospective single-center study of preoperative clinical predictors that increase the probability of extrathyroidal invasion of thyroid cancer was conducted. Data from 514 patients aged 5 to 81 years were processed. Patients underwent surgery for papillary thyroid cancer for the first time. Scope of the operation: extrafascial thyroidectomy. Central neck dissection. Lymphadenectomy. All patients had clinical signs of low risk of recurrence. The mean age of patients was 44.4 ± 14.5 years. There were 91 men (17.7%) and 423 women (82.3%). Patients were divided into two groups: group 1 with 169 patients with minimal extraorganic invasion aged 5 to 71 years, group 2 with 345 patients without invasion aged 10 to 81 years. The following features were taken into account for the analysis: 1) age of patients; 2) their sex; 3) the size of the dominant tumor. The results were statistically processed using a specialized statistical program StatPlus Pro v.7 (AnalystSoft Inc.) and Epitools statistical calculators (Ausvet, https://epitools.ausvet.com.au/). According to the results, both by age (mean age of patients in group 1 - 44.7 ± 14.4 years; mean age of patients in group 2 - 44.3 ± 14.6 years) and by sex (in group 1 – 30 men (17.8%), 139 women*

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(82.2%), in group 2 – 61 men (17.7%), 284 women (82.3%), the groups were almost identical, both groups were significantly (p <0.01) dominated by women. The size of the primary tumor in group 1 - 15.0 (10.0; 20.0) mm - was statistically significantly higher (p <0.001) than in the second - 10.0 (7.0; 15.0) mm. Most of patients (71.0%) with invasion had a primary tumor size > 10 mm, while in group 2 there were only 42.6% of such patients. Within the size ranges up to 10 mm, the probability of detection of invasion is 14.0% - 21.6%, while within the size ranges over 10 mm, it may be 41.9% - 50.0%. A tumor size of PTC over 10 mm, with a diagnostic strength of 61.9%, increases the risk of minimal extrathyroidal invasion. The average size of the primary tumor in the group of patients with minimal ETI is 15.0 (10.0; 20.0) mm, which is statistically significantly higher (p <0.001) than the same value in the group of patients without EIT - 10.0 (7.0; 15.0) mm. In patients with a PTC tumor size of less than 10 mm, the probability of minimal ETI ranges from 14.0% to 21.6%, while the probability of minimal ETI in patients with a tumor size over 10 mm ranges from 41.9% to 50.0%. Given that minimal ETI may be one of the factors of increased risk of PTC locoregional metastasis, surgery for PTC patients with a tumor size over 10 mm should be supplemented with central neck dissection, lymphadenectomy. A tumor size of PTC over 10 mm, with a diagnostic strength of 61.9%, increases the risk of minimal extrathyroidal invasion, which is also an argument in favor of central neck dissection, lymphadenectomy during surgery for patients with tumor size over 10 mm. The patients' age and sex cannot be the factors that increase the risk of minimal extrathyroidal invasion of papillary thyroid cancer.

Key words: papillary thyroid cancer, prognostic factor, metastasis, risk factors.

Introduction

Papillary thyroid carcinoma (PTC) is the most common malignancy of a thyroid gland; and although PTC has an excellent prognosis, metastasis to central lymph nodes is a common phenomenon. Studies have shown that metastases to the central lymph node basin are connected with an increased recurrence rate (Huseyin Celik, Ozgur Akgul, et al. 2017).

Extrathyroidal invasion (ETI) is defined as the spread of a primary tumor beyond the thyroid capsule and invasion of surrounding structures (e.g. prethyroid muscle, trachea, larynx, vascular network, esophagus, and recurrent laryngeal nerve). Extrathyroidal dilatation is well recognized as an important adverse prognostic factor and is used in several stage systems, including EORTC (European Organization Research Treatment Cancer), TNM classification, DeGroot et al, AGES (age, grade, ETE and size), AMES (age, metastases, ETE and size), and MACIS (metastases, age, completeness of resection, invasion and size) (Amanda Hu, MD, Jonathan Clark, Richard J. Payne, 2007).

ETI is a risk factor for PTC locoregional metastasis (Lishchynskyi P.O., et al., 2021). At the same time, patients with broad ETI have a higher risk of recurrence as compared to the patients with minimal ETI or thyroid tissue invasion (Zeming Liu, Yihui Huang, Sichao Chen, 2019).

Although minimal ETI may be a factor of increased risk of recurrence in patients with papillary thyroid cancer (Yin De-Tao.Yu, et al. 2016), however, the increased risk is not high in absolute terms, and in N0 patients the risk of recurrence is within the low-risk category of 3.5%. Minimal ETI has no effect on disease-related mortality and it should not alter the stage of the malignancy (Talia Diker-Cohen, et al. 2018).

It is a common knowledge that tumor size is also an important factor in staging the process according to the TNM classification. Larger tumors are prone to aggressive growth (Wei Sun et al., 2015).

The combination of tumor diameter and minimal ETI can be used as a reliable prognostic factor for persistence and can be easily used in clinical practice for the treatment of PTC patients with low or moderate risk of recurrence or persistence of the disease (Raffaella Forleo, et al. 2021). However, the clinical significance of minimal ETI depending on the primary tumor size has not been studied thoroughly (Lihua Liu et al. 2018).

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Moreover, given that the identification of the minimal ETI is possible only during the final histopathological study (Amanda Hu, MD, et al. 2007), there is a need to assess the existing preoperative clinical predictors that increase the probability of minimal ETI of papillary thyroid cancer in adipose tissue.

Aim

To assess preoperative clinical predictors that increase the probability of minimal extraorganic invasion of papillary thyroid cancer.

Methods

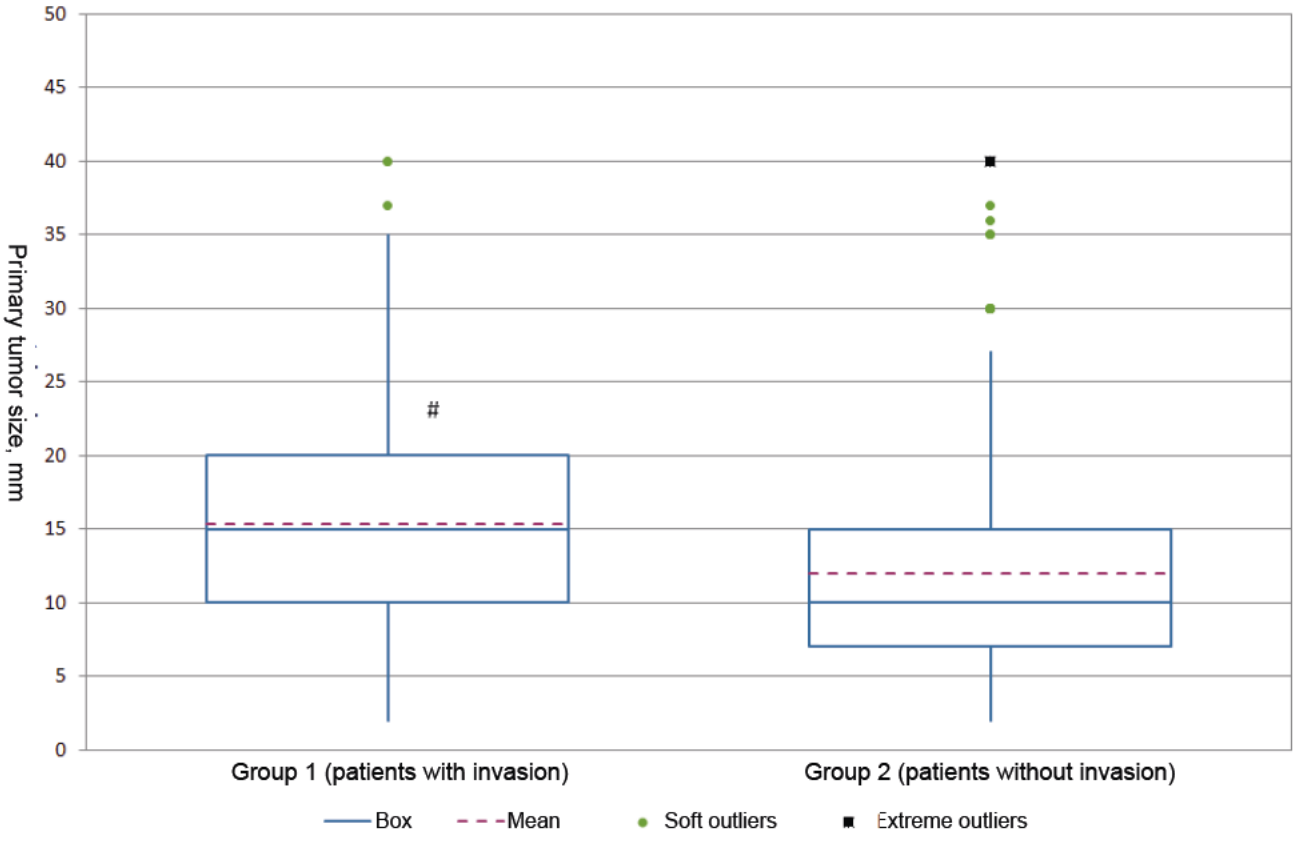
A retro-prospective single-center study of preoperative clinical predictors that increase the probability of extraorganic invasion of thyroid cancer was conducted. Data from 514 patients aged 5 to 81 years were processed. Patients underwent surgery for papillary thyroid cancer for the first time. Scope of the operation: extrafascial thyroidectomy. Central neck dissection. Lymphadenectomy. At the preoperative stage, all patients underwent ultrasound of the neck with Philips HD 11 XE and a linear probe with a frequency of 3-12 MHz. All patients had clinical signs of low risk of recurrence. The mean age of patients was 44.4 ± 14.5 years. There were 91 men (17.7%) and 423 women (82.3%). Patients were divided into two groups: group 1 with 169 patients with minimal extraorganic invasion aged 5 to 71 years, group 2 with 345 patients without invasion aged 10 to 81 years.

The following features were taken into account for the analysis: 1) age of patients; 2) their sex; 3) the size of the dominant tumor.

The results were statistically processed using a specialized statistical program StatPlus Pro v.7 (AnalystSoft Inc.) and Epitools statistical calculators (Ausvet, https://epitools.ausvet.com.au/).

The results of calculations for numerical data series that were subject to the normal law of distribution were presented as mean (M) and standard deviation (SD), in other cases - median (Me) and the first and third quantiles (Q1; Q3). For the operational characteristics obtained from

Fig. 1. Box plot for the 'primary tumor size'.



Note. # – difference between the groups is significant ($p<0.001$).

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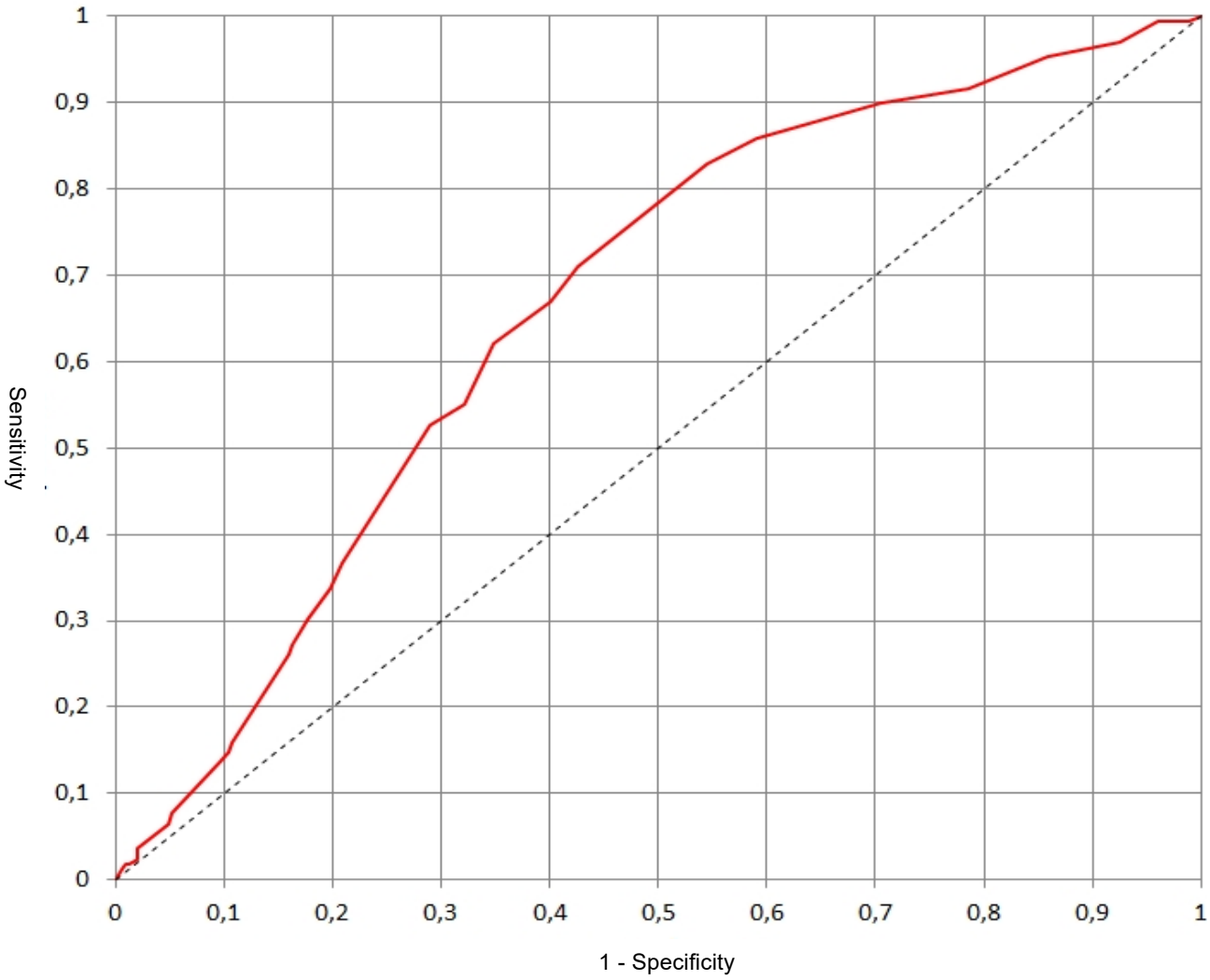

Fig. 2. ROC curve for the 'primary tumor size'.

the ROC analysis, 95% confidence interval (CI) was given.

Student's parametric criterion for independent groups and, in other cases, the non-parametric Mann-Whitney test were used to compare data series that were subject to the normal law of distribution. Particle comparison was performed using Fisher's angular transformation.

When performing ROC analysis, the area under the ROC curve was determined by the D. Delong's method.

Results

According to the study results, both by age (mean age of patients in group 1 - 44.7 ± 14.4 years; mean age of patients in group 2 - 44.3 ± 14.6 years) and by gender (in group 1 - 30 men (17.8%), 139 women (82.2%), in group 2 - 61 men (17.7%), 284 women (82.3%), the groups were almost identical, both groups were significantly ($p < 0.01$) dominated by women.

The size of the primary tumor in group 1 - 15.0 (10.0; 20.0) mm - was statistically significantly higher ($p < 0.001$) than in group 2 - 10.0 (7.0; 15.0) mm, which is clearly shown on the box plots ('whiskers' were determined by the Tukey method) (Fig. 1).

Availability of such differences encouraged us to conduct an ROC analysis to determine the appropriate cut-off value to decide on the differentiation of these groups of patients. The obtained ROC curve is shown on Fig. 2.

Area under AUC curve = 0.665 (95% CI: 0.617; 0.713), which corresponds to the average quality of the model.

In the case where it is necessary to ensure the best ratio of sensitivity and specificity, which is

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determined using the Youden index, which was 0.284 in our study, the cut-off value was > 10 mm (decision rule: X> T). So, the sensitivity was 0.710 (95% CI: 0.642; 0.778), and the specificity was 0.574 (95% CI: 0.522; 0.626).

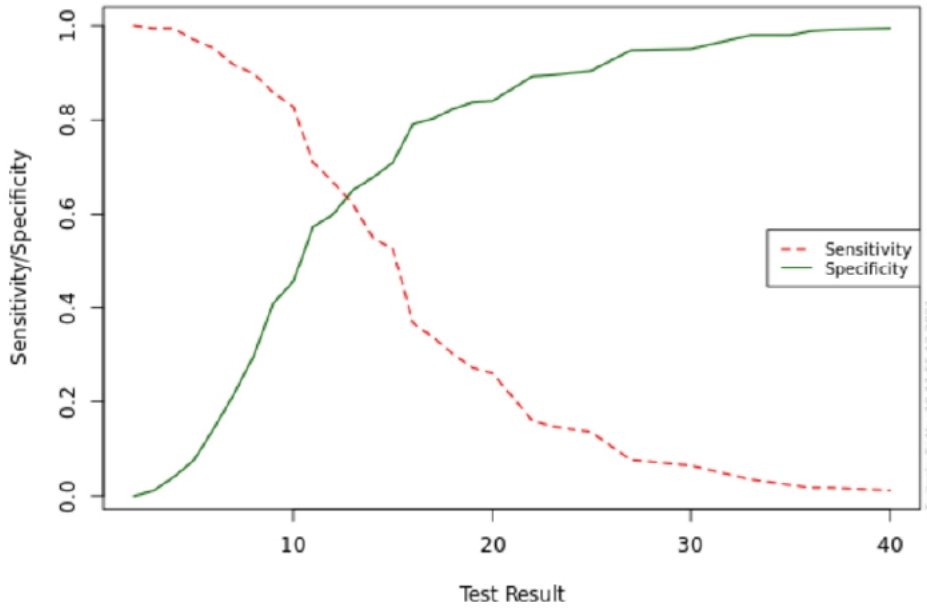

Fig. 3. Sensitivity and specificity graphs.

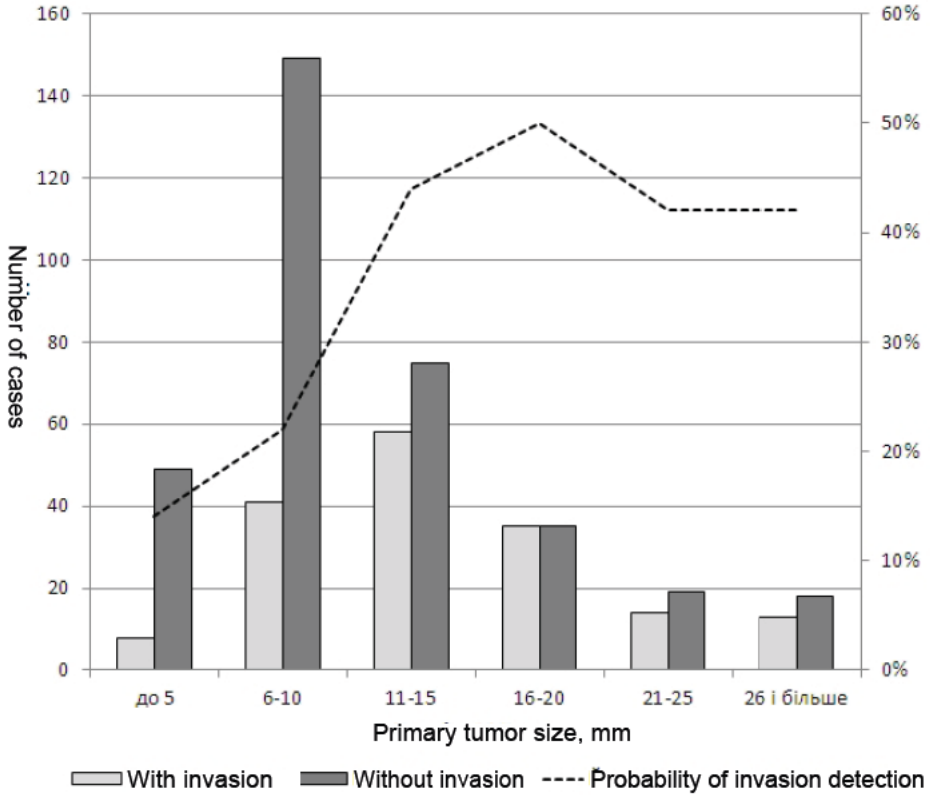

Fig.4. Distribution of incidence of observations in different ranges of tumor sizes in groups of patients and the corresponding probability of invasion.

The greatest proximity of sensitivity and specificity (approximately 0.635), which may serve as another criterion for choosing the cut-off value, is achieved when the primary tumor size is about 12-13 mm as illustrated by graphs on Fig. 3.

With a cut-off value > 12 mm, the sensitivity of 0.621 (95% CI: 0.544; 0.695) and the specificity of 0.652 (95% CI: 0.599; 0.702) are achieved.

It should be noted that the vast majority of patients (71.0%) with invasion had a primary tumor size > 10 mm, while in group 2 there were only 42.6% of such patients.

The incidence of fat invasion averages 0.329 or 32.9% (169 cases out of 514). However, it significantly depends on the primary tumor size, which is well illustrated by the combined diagram in Fig. 4. Within the size ranges up to 10 mm, the probability of detection of invasion is 14.0% - 21.6%, while within the size ranges over 10 mm, it may be 41.9% - 50.0%.

In general, almost half of the patients (48.1 %) in the study groups had a primary tumor size of ≤10 mm.

Another criterion in decision-making may be predetermined sensitivity, specificity or other characteristics of the test. For example, choosing cut-off

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Cut-off value, mm	Sensitivity	Specificity	Prognostic significance of a positive test result	Prognostic significance of a positive test result	Overall diagnostic strength, %
>8	0,858 (0,796; 0,907)	0,409 (0,356; 0,463)	0,416 (0,390; 0,442)	0,855 (0,799; 0,897)	55,6 (51,2; 60,0)
>9	0,828 (0,763; 0,882)	0,455 (0,402; 0,510)	0,427 (0,398; 0,456)	0,844 (0,792; 0,885)	53,4 (51,2; 62,1)
>10	0,710 (0,635; 0,772)	0,574 (0,520; 0,627)	0,449 (0,411; 0,488)	0,802 (0,758; 0,839)	61,9 (57,5; 66,1)
>11	0,667 (0,592; 0,739)	0,600 (0,546; 0,652)	0,450 (0,409; 0,492)	0,787 (0,746; 0,823)	62,3 (57,9; 66,5)
>12	0,621 (0,544; 0,695)	0,652 (0,599; 0,702)	0,467 (0,421; 0,513)	0,779 (0,741; 0,812)	64,2 (59,9; 68,4)
>13	0,550 (0,472; 0,627)	0,678 (0,626; 0,727)	0,456 (0,406; 0,507)	0,755 (0,720; 0,787)	63,6 (59,3; 67,8)
>14	0,527 (0,449; 0,604)	0,710 (0,659; 0,758)	0,471 (0,417; 0,526)	0,754 (0,720; 0,785)	64,2 (60,7; 69,1)

Table 1. Test performance (with CI of 95%) for some cut-off value

values in the range from 9 to 15 mm, one can vary the test sensitivity from 0.858 to 0.527 when changing the specificity from 0.409 to 0.710 (Table 1).

Discussion

According to our data, minimal extraorganic invasion may be one of the factors of increased risk of locoregional metastasis of papillary thyroid cancer ($p < 0.01$), with a diagnostic strength of 64.8% (Lishchynskyi P.O. et al., 2021).

The sensitivity of preoperative diagnostic imaging methods does not allow us to detect extraorganic invasion of primary tumor of papillary thyroid cancer at the microscopic level (in adipose tissue), therefore we assessed the relation between preoperative characteristics such as the patient's age, sex, the size of the primary tumor with the incidence of minimal extraorganic invasion.

According to the results of the study, both by age and sex, the groups were almost identical. At the same time, the average size of the primary tumor in group 1 was 15.0 (10.0; 20.0) mm, which is statistically significantly higher ($p < 0.001$) as compared to the same indicator in group 2 - 10.0 7.0; 15.0) mm. When building the ROC curve, the area under AUC curve = 0.665, which corresponds to the average quality of the model. Within the size ranges up to 10 mm, the probability of detection of invasion is 14.0% - 21.6%, while within the size ranges over 10 mm, it may be 41.9% - 50.0%.

Tumor size of papillary thyroid cancer over 10 mm, with the diagnostic strength of 61.9%, increases the risk of minimal extrathyroidal invasion, while tumor size over 12 mm increases the risk of minimal extrathyroidal invasion with the diagnostic strength of 64.2%.

The results of our study are similar to the results obtained by the colleagues from China in the study: "Predictors for central lymph node metastases in CN0 papillary thyroid microcarcinoma (mPTC): A retrospective analysis of 1304 cases", which reported that the presence of metastases in central cervical lymphatic nodes is associated with tumor size (> 0.5 cm), capsular and extrathyroidal invasion (Qiang Zhang, et al. 2019).

Conclusions

The average size of the primary tumor in the group of patients with minimal ETI is 15.0 (10.0; 20.0) mm, which is statistically significantly higher ($p < 0.001$) than the same value in the group of patients without ETI - 10.0 (7.0; 15.0) mm.

In patients with a tumor size of less than 10 mm, the probability of minimal extraorganic invasion ranges from 14.0% to 21.6%, while the probability of minimal ETI in patients with a PTC tumor size over 10 mm ranges from 41.9% to 50.0%.

Given that minimal ETI may be one of the factors of increased risk of locoregional metastasis, surgery for patients with a tumor size over 10 mm should be supplemented with central neck dissection, lymphadenectomy.

A tumor size of PTC over 10 mm, with a diagnostic strength of 61.9%, increases the risk of minimal extrathyroidal invasion, which is also an argument in favor of central neck dissection,

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lymphadenectomy during surgery for patients with tumor size over 10 mm.

According to our data, the patients' age and sex cannot be the factors that increase the risk of minimal extraorganic invasion of papillary thyroid cancer.

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This study did not receive external funding.

Conflict of interest

None of the authors re- ceived research grants, speaker's fees from any companies and is not a member of commissions.

Consent to publication

All authors have read and approved the final version of the manuscript. All authors have agreed to publish this manuscript.

ORCID ID and AUTHORS CONTRIBUTION

0000-0003-3586-0468 (A, B, C, D) Lishchynskyi Pavlo
0000-0001-9554-4817 (A, C, E) Palamarchuk Volodymyr
0000-0002-4434-7298 (B, C) Kuts Volodymyr
0000-0002-8540-9192 (B) Mazur Oleh
0000-0002-5039-1324 (E,F) Zemskov Sergii
0000-0002-1329-279X (E,F) Tovkai Oleksandr
0000-0003-4033-3195 (F) Dronov Olexii

A – Research concept and design, B – Collection and/or assembly of data, C – Data analysis and interpretation, D – Writing the article, E – Critical revision of the article, F – Final approval of article

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Клінічні предиктори мінімальної екстратиреоїдної інвазії папілярного раку щитоподібної залози у жирову клітковину

Ліщинський Павло[1], Паламарчук Володимир[1], Мазур Олег[1], Куц Володимир[2], Земсков Сергій[3], Товкай Олександр[4], Дронов Олексій[5]

[1] Відділ ендокринної хірургії УНПЦЕХ ТЕОіТ, Київ, Україна

[2] Відділ інформаційно-комп›ютерних технологій НІФП ім. Ф.Г. Яновського НАМНУ, Київ, Україна

[3] Проректор з наукової роботи та інновацій Національного медичного університету ім. О.О. Богомольця, Київ, Україна

[4] Директор УНПЦЕХ ТЕОіТ, Київ, Україна

[5] Кафедра загальної хірургії №1 Національного медичного університету ім. О.О. Богомольця, Київ, Україна

Address for correspondence:

Lishchynskyi Pavlo

E-mail: endosurg88@ukr.net

Анотація: Екстратиреоїдна інвазія (ЕТІ) папілярного раку щитоподібної залози (ПРЩЗ) є фактором ризику локорегіонарного метастазування. Клінічне значення мінімальної ЕТІ залежно від розміру первинної пухлини не було добре вивчено. Комбінація діаметра пухлини та мінімальної ЕТІ, може бути використана як надійний прогностичний фактор для персистенції захворювання. Враховуючи те, що виявлення мінімальної ЕТІ можливе лише під час остаточного патогістологічного дослідження, виникає необхідність оцінки наявних доопераційних клінічних предикторів, які підвищують ймовірність мінімальної ЕТІ ПРЩЗ. Оцінити доопераційні клінічні предиктори, які підвищують ймовірність мінімальної екстраорганної інвазії папілярного раку щитоподібної залози. Проведено ретро-проспективне моноцентрове, дослідження передопераційних клінічних предикторів, що підвищують ймовірність екстраорганної інвазії раку щитоподібної залози. Опрацьовано дані 514 пацієнтів у віці від 5 до 81 років. Хворі вперше прооперовані з приводу папілярного раку щитоподібної залози. Обсяг операції: екстрафасціальна тиреоїдектомія. Центральна дисекція шиї. Лімфаденектомія. Всі хворі мали клінічні ознаки низького ризику рецидиву захворювання. Середній вік пацієнтів становив 44,4 ± 14,5 років. Чоловіків – 91 (17,7 %), жінок – 423 (82,3 %). Пацієнти були розподілені на дві групи: 1 група – 169 хворих з мінімальною екстраорганною інвазією у віці від 5 до 71 років. (; 2 група – 345 хворих без інвазії у віці від 10 до 81 року Для проведення аналізу враховувались такі ознаки: 1) вік; 2) стать; 3) розмір домінантної пухлини. Статистичну обробку отриманих результатів здійснювали за допомогою спеціалізованої статистичної програми StatPlus Pro v.7 (AnalystSoft Inc.) та статистичних калькуляторів Epitools (Ausvet, https://epitools.ausvet.com.au/). За результатами дослідження, як за віком (середній вік пацієнтів 1 групи – 44,7 ± 14,4 років; середній вік пацієнтів 2 групи – 44,3 ± 14,6 років), так і за гендерною ознакою (у 1 групі чоловіків – 30 (17,8 %), жінок – 139 (82,2 %); у 2 групі чоловіків – 61 (17,7 %), жінок – 284 (82,3 %), групи були практично тотожні. В обох групах достовірно ($p<0,01$) переважали жінки. Розміри первинної пухлини у 1-й групі – 15,0 (10,0; 20,0) мм – були статистично значущо вищі ($p<0,001$), ніж у другій – 10,0 (7,0; 15,0) мм. Переважна більшість хворих (71,0 %) з інвазією мали розміри первинної пухлини >10 мм, натомість у групі 2 таких хворих було лише 42,6 %. У діапазонах розмірів до 10 мм, ймовірність виявлення інвазії становить від 14,0 % до 21,6 %, натомість у діапазонах розмірів більших за 10 мм, вона коливається у межах від 41,9 % до

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50,0 %. Розмір пухлини ПРЩЗ більше 10 мм, з діагностичною ефективністю 61,9%, підвищує ризик мінімальної екстратиреоїдної інвазії. Середній розмір первинної пухлини у групі пацієнтів з мінімальною ЕТІ – 15,0 (10,0; 20,0) мм, що статистично значущо вище (p<0,001) за цей показник у групі пацієнтів без ЕТІ – 10,0 (7,0; 15,0) мм. У пацієнтів з розміром пухлини ПРЩЗ меншою за 10 мм, ймовірність виявлення мінімальної ЕТІ становить від 14,0% до 21,6%, натомість ймовірність виявлення мінімальної ЕТІ у пацієнтів з пухлиною ПРЩЗ більшою за 10 мм, складає від 41,9% до 50,0%. Враховуючи те, що мінімальна ЕТІ може слугувати одним із факторів підвищеного ризику локорегіонального метастазування ПРЩЗ, пацієнтам, з розміром пухлини ПРЩЗ більше 10 мм, оперативне втручання слід доповнювати центральною дисекцією шиї, лімфаденектомією. Розмір пухлини ПРЩЗ більше 10 мм, з діагностичною ефективністю 61,9%, підвищує ризик мінімальної екстратиреоїдної інвазії, що також є аргументом на користь виконання центральної дисекції шиї, лімфаденектомії під час оперативного втручання для пацієнтів з розміром пухлини більше 10 мм. Вік і стать хворих не можуть слугувати факторами, що підвищують ризик мінімальної екстраорганної інвазії папілярного раку щитоподібної залози.

Ключові слова: папілярний рак щитоподібної залози, фактори ризику, метастази, прогностичний фактор.