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Malignancy risk for thyroid nodules larger than 4 cm and diagnostic reliability of ultrasound-guided FNAB results

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ABSTRACT

Objective: Our aim in the present study was to investigate the relation between thyroid nodule diameter and malignancy, and the diagnostic accuracy of fine needle aspiration biopsy (FNAB) for thyroid nodules larger than 4 cm.

Material and Methods: Preoperative patient demographics such as age and gender, thyroid nodule diameter, FNAB results and postoperative pathology results were recorded. The relation between age, gender, thyroid nodule size of the patients and malignancy was examined. Also, the sensitivity, specificity, false negativity, false positivity and accuracy rates of FNBA of the patients whose thyroid nodule size was lower than 4 cm and the ones whose thyroid nodule size was higher than 4 cm were analyzed.

Results: There was no significant difference between males and females in terms of malignancy rate (p= 0.15). There was no significant relation between malignancy and patient age (p= 0.92). No significant difference was found between the group with thyroid nodule diameter of > 4 cm and the group thyroid with nodule diameter of < 4 cm in terms of malignancy (p= 0.91). In the group with thyroid nodule diameter of > 4 cm, sensitivity, specificity, false negativity, false positivity, and accuracy rates of FNAB were 15%, 100%, 84%, 0%, and 70%, respectively. In the group with thyroid nodule diameter of < 4 cm, sensitivity, specificity, false negativity, false positivity, and accuracy rates of FNAB were 53%, 100%, 46%, 0% and 80%, respectively.

Conclusion: Our study put forward that thyroid nodule diameter is not the only predictor parameter whilst predicting malignancy. However, it was observed that FNAB sensitivity and false negativity were higher when the thyroid nodules with > 4 cm diameter were compared to the thyroid nodules with < 4 cm diameter.

Keywords: Thyroid nodule diameter, malignancy, fine needle aspiration biopsy, false negativity

INTRODUCTION

Thyroid nodules are very common in the general population. Clinically palpable nodules are observed in 4-7% of the population (1). Prevalence rate is higher when the thyroid gland is evaluated with imaging methods. Thyroid nodules can be found in 17-67% of the adult population when evaluated with cervical ultrasonography (USG) (2). Although most thyroid nodules are benign, the prevalence of thyroid cancer has recently risen dramatically (3). Malignancy rate in thyroid nodules is about 5%-20% (4). In case a nodule is detected on physical examination, the critical question is whether it is benign or malignant. Standard thyroid nodule evaluation protocol consists of patient's history, physical examination, serum thyroid stimulating hormone (TSH) level, cervical USG, and fine needle aspiration biopsy (FNAB). Consideration of clinical factors combined with USG findings gives a clue about the malignancy of the nodule. Particularly hypoechogenic nature of the nodule, presence of calcification, irregular or infiltrative borders, and increased vascularity of the nodule are important predictors of malignancy (5,6). As a reliable, rapid and low-cost method, FNAB is accepted as a gold standard diagnostic tool for the assessment of thyroid nodules. With a false negativity rate under 5%, FNAB is widely used by clinicians. False negativity and non-diagnostic cytology rates are reduced when FNAB is performed under USG guidance (2,7). There are studies reporting that increased nodule diameter is associated with malignancy risk and can be used

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as a predictor of malignancy (8,9). On the other hand, there are also studies reporting that there is no association between nodule diameter and malignancy risk (10,11). Some authors recommend thyroidectomy for nodules larger than 4 cm even when FNAB result is benign due to increased malignancy risk and increased false negativity rate (12,13). Yet, other studies show no difference between small and large nodules with regard to the false negativity of FNAB (14,15).

In many centers, the patient is referred to surgery when the nodule size is greater than 4 cm even if FNAB result is negative. Our aim in the present study was to examine the validity of this approach, to investigate the relationship between nodule diameter and malignancy, and the diagnostic accuracy of FNAB for nodules larger than 4 cm.

MATERIAL and METHODS

The study included 322 patients who underwent thyroid surgery in our clinic between October 2010 and January 2015 due to the diagnosis of nodular goiter. Data were obtained retrospectively from patient files. The study was carried out in accordance with the declaration of Helsinki. Cystic and complex (solid + cystic) nodules were excluded from the study.

Preoperative patient demographics such as age and gender, nodule diameter, FNAB results and postoperative pathology results were recorded. FNAB was performed under USG guidance by radiologists in a radiology clinic. For solitary nodules, FNAB was performed on that nodule, whereas for multinodular cases, FNAB was performed on the nodule showing malignant characteristics in ultrasonographic assessment, or on the largest (dominant) nodule. Nodule diameters were recorded from USG reports in the unit of cm. FNAB results were categorized according to Bethesda classification as non-diagnostic (category 1), benign (category 2), atypia of undetermined significance (AUS)/follicular lesion of undetermined significance (FLUS) (category 3), follicular neoplasm/suspicious for a follicular neoplasm (category 4), suspicious for malignancy (category 5), and malignancy (category 6) groups. Surgical indications for patients with benign and non-diagnostic FNAB results in Bethesda categories 1 and 2 were cosmetic problems and compression findings for nodules larger than 4 cm, whereas for nodules smaller than 4 cm, surgical indications were presence of clinical symptoms (being dysphagia or disphonia, nodule's fast growth) and the existence of nodule malignancy chance radiologically (nodule being hypoechoic, having micro qualifications, nodule having irregular sidelines, increase in vascularity in Doppler). Thyroidectomy was performed by surgeons experienced in the field of endocrine surgery. For evaluation of sensitivity, specificity, false negativity, false positivity and accuracy of FNAB, Bethesda category 2 was accepted as a negative result, while category 6 was accepted as a positive result. Inadequate and suspicious categories were not included in the analysis.

The relation between age, gender, nodule size of the patients and malignancy was examined. Also, the sensitivity, specificity, false negativity, false positivity, and accuracy rates of FNBA of the patients whose nodule size was lower than 4 cm and the ones whose nodule size was higher than 4 cm were analyzed.

Chi-square and independent t-tests were used in statistical analysis. Normality assessment was made with Kolmogorov-Smirnov test. $p< 0.05$ was considered significant.

RESULTS

Of the 322 patients included, 54 (16.8%) were males and 268 (83.2%) were females. Mean age was 48.4 ± 13.9 years with a range of 13-91 years. 222 (68.9%) patients had multiple nodules, whereas 100 (31.1%) patients had solitary nodules. 257 (79.8%) patients had nodules with a diameter of < 4 cm, while 65 (20.2%) patients had nodules with a diameter of > 4 cm. Preoperative FNAB results were nondiagnostic in 39 (12.1%) patients; benign in 131 (40.7%) patients; AUS/FLUS in 14 (4.3%) patients; follicular neoplasm/suspicious for follicular neoplasm in 107 (33.2%) patients; and suspicious for malignancy in 5 (1.6%), Malign cytology was observed in 26 (8.1%) patients. Mean nodule diameter was 2.8 ±-1.3 cm (0.5-9.5 cm). Types of surgery were total thyroidectomy in 266 (82.6%) patients, lobectomy in 53 (16.4%) patients and complementary thyroid surgery in 3 (0.9%) patients. Postoperative final pathology results were benign in 195 (60.6%) patients and malignant in 127 (39.4%) patients. Among patients with malignant results, detected histopathological types were papillary carcinoma in 106 patients, Hurthle cell carcinoma in 9 patients, follicular carcinoma in 6 patients, medullary carcinoma in 2 patients, poorly differentiated carcinoma in 2 patients, and anaplastic carcinoma in 1 patient. Malignancy was seen in 101 (37.6%) of the female patients and 26 (48.1%) of the male patients (Table 1). There was no significant difference between males and females in terms of malignancy rate (p= 0.15). Mean age of the patients in the malignant group was 48.7 (22-85) years, and that of the patients in the benign group was 49.3 (13-91) years. There was no significant relationship between malignancy and patient age (p= 0.92). Malignancy was seen in 26 (40%) of the 65 patients with a nodule diameter of > 4 cm and in 101 (39.2%) of 257 patients with a nodule diameter of < 4 cm. No significant difference was found between the group with a

Table 1. Malignant and benign distribution according to sex

	Histopathology		
Sex	Benign	Malign	Total
Male	28	26	54
Female	167	101	268
Total	195	127	322

nodule diameter of > 4 cm and the group with a nodule diameter of < 4 cm in terms of malignancy (p= 0.91). In the group with a nodule diameter of > 4 cm, malignancy was observed in 3 of 10 patients in non-diagnostic FNAB category, 11 of 35 patients in benign category, none of the patients in AUS/FLUS category, 10 of 16 patients in follicular neoplasm/suspicious for follicular neoplasm category, and both of the 2 patients with malignant FNAB results while in the group with a nodule diameter of < 4 cm, malignancy was observed in 3 of 29 patients in non-diagnostic category, 21 of 96 patients in benign category, 3 of 12 patients in AUS/FLUS category, 47 of 91 patients in follicular neoplasm/suspicious for follicular neoplasm category, 3 of 5 patients in suspicious for malignancy category, and in all of the 24 patients in the malignancy category (Tables 2,3). In general, the sensitivity, specificity, false negativity, false positivity, and accuracy rates of FNAB were 44%, 100%, 55%, 0%, and 70%, respectively. In the group with a nodule diameter of > 4 cm, sensitivity, specificity, false negativity, false positivity and accuracy rates of FNAB were 15%, 100%, 84%, 0% and 70%, respectively. In the group with a nodule diameter of < 4 cm, sensitivity, specificity, false negativity, false positivity and accuracy rates of FNAB were 53%, 100%, 46%, 0% and 80%, respectively (Table 4).

Table 2. Fine needle aspiration biopsy results in the nodule diameter > 4 cm group

	Postoperative histopathology		
FNAB	**Benign**	**Malign**	**Total**
Non-diagnostic	7	3	10
Benign	24	11	35
AUS/FLUS	2	0	2
Follicular neoplasm/suspicious	6	10	16
Malignancy positive	0	2	2
Total	39	26	65

FNAB: Fine needle aspiration biopsy; AUS/FLUS: Atypia of undetermined significance/follicular lesion of undetermined significance.

Table 3. Fine needle aspiration biopsy results in the nodule diameter < 4 cm group

	Postoperative histopathology		
FNAB	**Benign**	**Malign**	**Total**
Non-diagnostic	26	3	29
Benign	75	21	96
AUS	9	3	12
Follicular neoplasm/suspicious	44	47	91
Malignency suspicious	2	3	5
Malignancy positive	0	24	24
Total	156	101	257

FNAB: Fine needle aspiration biopsy; AUS: Atypia of undetermined significance.

DISCUSSION

In case of detection of a thyroid nodule, determination of its malignancy probability is of key importance for the clinician. Numerous studies have been conducted to investigate many parameters to be used in the prediction of the malignancy-risk of thyroid nodules. Studies examining the relationship between age and malignancy risk of nodules have shown contradicting results. Pinchot et al. have reported a higher prevalence of thyroid cancer among the elderly population in comparison to the young adults (16). Godazaneh; however, has found a higher prevalence of thyroid cancer among young adults compared to the elderly (17). On the other hand, in their studies, Rosario et al. and Rapari et al. have reported that there is no significant association between age and malignancy (8,18). In our study, mean patient age was similar in benign and malignant groups (48.7 and 49.3 years, respectively), and no significant association was found between age and malignancy (p= 0.92> 0.05). Raparia et al. have studied patients with FNAB results as suspicious for follicular carcinoma or Hurthle cell neoplasm or suspicious for malignancy, and they have found a higher prevalence of malignancy among males in comparison to females (8). Kim et al. have studied patients with thyroid nodules larger than > 4 cm, and they have reported that there is no significant difference between males and females with regard to malignancy (p= 0.78) (12). In our study, a significant difference was not found between male and female groups in terms of malignancy (p= 0.15).

Many studies have examined the association between thyroid nodule size and malignancy risk and reported contradicting results. In their study including patients with FNAB results as suspicious for follicular carcinoma or Hurthle cell neoplasm or

Table 4. Sensitivity, specificity, false negativity, false positivity and accuracy rates of fine needle aspiration biopsy

FNAB	Sensitivity	Specifity	False negativity	False positivity	Accuracy
> 4 cm	15%	100%	84%	0%	70%
< 4 cm	53%	100%	46%	0%	80%
Total	44%	100%	55%	0%	70%

FNAB: Fine needle aspiration biopsy, AUS/FLUS: Atypia of undetermined significance/follicular lesion of undetermined significance.

suspicious for malignancy, Rapari et al. have reported a higher frequency of malignancy among patients with nodules larger than 2 cm (p< 0.001) (8). McCoy et al. have reported a higher prevalence of malignancy for nodules ≥ 4 cm (9). In a meta-analysis, Hammad et al. have examined the relationship between nodule size and malignancy and categorized nodules in three groups based on their diameter as < 3 cm, 3-5.9 cm, and ≥ 6 cm. In a comparison of 3-5.9 cm group with < 3 cm group, they have found higher malignancy risk in the group with nodule size between 3-5.9 cm (p= 0.02) (< 3 cm). In a comparison of ≥ 6 cm group with < 3 cm group, they have found that malignancy risk is lower in ≥ 6 cm group (p< 0.001) (19). In another study, McHenry et al. have reported that the mean diameter of malignant nodules is lower than that of benign nodules (p< 0.001), and therefore, the nodule diameter could not be a predictor of malignancy (10). In their study including patients with nodule size > 4 cm, Kim et al. have not found an association between nodule diameter and malignancy (p= 0.13) (12). Godazandeh et al. have not determined a significant difference between patients with nodule size > 4 cm and < 4 cm in terms of malignancy rate (p= 0.29) (17). Megwalu et al. have studied nodules ≥ 4 cm and have not detected an association between nodule size and malignancy (p= 0.7) (20). In our study, there was no significant difference between the > 4 cm group and the < 4 cm group in terms of malignancy (p= 0.91). Conflicting results from various studies suggest that nodule size on its own is not a reliable parameter for predicting malignancy. Deciding on medical follow-up or surgery, based on the nodule diameter alone, would not be a correct approach.

FNAB is currently considered a gold standard diagnostic tool for the evaluation of thyroid nodules. Diagnostic accuracy is particularly higher when it is performed under USG guidance and in experienced hands. Nonetheless, diagnostic accuracy of FNAB is controversial, especially for large nodules. In their study including patients with nodules of > 4 cm, Kim et al. have found general false negativity rate as 11.9%, and because of such a high rate, they have recommended consideration of surgery in case of suspicious USG findings for nodules of > 4 cm, even if FNAB is negative (12). In another study, Wharry et al. have studied patients with nodules of ≥ 4 cm and found false negativity rate of FNAB as 10.4%. They have reported that lack of suspicious USG findings would not rule out malignancy and that therefore, at least lobectomy should be considered for nodules ≥ 4 cm (13). In their study, Godazandeh et al. have found that sensitivity of FNAB is lower and false negativity rate is higher when nodule size is < 4 cm (17). Giles et al. have compared patients with a nodule size of < 3 cm and ≥ 3 cm, and they have reported that false negativity rate is higher when nodule size is ≥ 3 cm. They have stated that thyroidectomy can be considered in patients with a ≥ 3 cm nodule even if FNAB is reported as benign (21). In their study, Koo et al. have categorized thyroid nodules as ≤ 0.5, > 0.5-1, > 1-2, > 2-4, and > 4 cm. They have found high false negativity rate (50%) in the > 4 cm group and recommended frequent FNAB for patients with a > 4 cm nodule even though FNAB is reported as benign (22). Beştepe et al. have reported that false negativity rates of ≥ 4 cm nodules is two times higher than the nodules between the sizes of 1-3.9 cm (23). By contrast to these studies, Shrestha et al. have categorized thyroid nodules in three groups as 0.5-0.9 cm, 1-3.9 cm, and ≥ 4 cm. They have found higher false negativity rate in the 0.5-0.9 cm group and stated that greater nodule diameter should not automatically direct physicians towards thyroidectomy (14). Albuja-Cruz et al. have examined patients with < 4 cm and ≥ 4 cm nodules and reported that diagnostic reliability of FNAB is not influenced by the nodule size. They have recommended not to use nodule size as a single independent factor while making the decision on thyroidectomy for ≥ 4 cm nodules (15). Megwalu et al. have found false negativity rate of FNAB as 0% in their study with ≥ 4 cm nodules, and they have recommended not to perform thyroidectomy automatically in every patient with ≥ 4 cm nodule and a benign FNAB result (20). Kuru et al. have found that false negative rates are 1.3% and 4.3% when they have compared < 4 cm nodules and ≥ 4 cm nodules, respectively. They have stated that FNAB's false negativity rates are lower in < 4 cm nodules and ≥ 4 cm nodules upon comparing ≥ 4 cm nodules with nodules between the sizes of 1-3.9 cm (24). In the present study, when > 4 cm and < 4 cm nodules were compared, it was found that FNAB had lower sensitivity and higher false negativity rate for nodules > 4 cm. In comparison to the literature data, lower sensitivity and higher false negativity rates were found in the present study. Accuracy of FNAB results may vary depending on several factors such as adequacy of sample volume, sampling from correct site, and accurate interpretation of the results. Therefore, the validity of the results of FNAB are significantly dependent on the experience of the pathologist that is in charge of the process of examination of the cytology samples and the radiologist who performs the procedure. Different findings in our series regarding FNAB results may be attributed to such factors.

Major limitation of the present study was its retrospective and single-centered design.

CONCLUSION

Our study put forward that nodule diameter was not the only predictor parameter whilst predicting the malignancy. However, it was observed that FNAB sensitivity and false negatively were higher when the nodules with a > 4 cm diameter were compared to the nodules with a < 4 cm diameter.

Ethics Committee Approval: Ethics committee approval was not obtained because the study was a retrospective file screening study.

Informed Consent: As the study was a retrospective file screening study, informed consent was not obtained.

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4 cm'den daha büyük tiroid nodüllerinde malignite riski ve ultrason eşliğindeki İİAB sonuçlarının tanısal güvenirliliği

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ÖZET

Giriş ve Amaç: Bu çalışmadaki amacımız tiroid nodül çapı ile malignite arasındaki ilişkiye ve 4 cm' den büyük tiroid nodüllerinde ince iğne aspirasyon biyopsisi (İİAB)'nin tanısal doğruluğunu araştırmak idi.

Gereç ve Yöntem: Hastaların ameliyat öncesi yaş, cinsiyet gibi demografik özellikleri, tiroid nodül çapları, İİAB sonuçları ve ameliyat sonrası patoloji sonuçları kaydedildi. Yaş, cinsiyet ve tiroid nodül çapı ile malignite arasındaki ilişki araştırıldı. Ayrıca tiroid nodül çapı > 4 cm ve < 4 cm olan hastalarda İİAB'nin duyarlılığı, özgüllüğü, yanlış negatifliği, yanlış pozitifliği ve doğruluğu değerlendirildi.

Bulgular: Kadın ve erkek grup malignite açısından karşılaştırıldığında iki grup arasında anlamlı bir fark bulunamadı (p= 0.15). Hastaların yaşları ile malignite arasında anlamlı bir ilişki bulunamadı (p= 0.92). Tiroid nodül çapı > 4 cm olan grup ile tiroid nodül çapı < 4 cm olan grup arasında malignite açısından anlamlı bir fark bulunamadı (p= 0.91). Tiroid nodül çapı > 4 cm olan grupta İİAB'nin sensivite, spesifite, yanlış negatiflik, yanlış pozitiflik ve doğruluk oranları sırasıyla %15, %100, %84, %0 ve %70 idi. Tiroid nodül çapı < 4 cm olan grupta İİAB'nin sensivite, spesifite, yanlış negatiflik, yanlış pozitiflik ve doğruluk oranları sırasıyla %53, %100, %46, %0 ve %80 idi.

Sonuç: Çalışmamız, tiroid nodül çapının tek başına maligniteyi öngörmede güvenilir bir parametre olmadığını ortaya koydu. Fakat > 4 cm tiroid nodüllerinde < 4 cm nodüllerle kıyaslandığında İİAB'nin duyarlılığının daha düşük ve yanlış negatiflik oranının daha yüksek olduğu bulundu.

Anahtar Kelimeler: Tiroid nodül çapı, malignite, ince iğne aspirasyon biyopsisi, yanlış negatiflik

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