Initially Nondiagnostic Ulrasound-Guided Fine-Needle Aspiration Biopsy of Thyroid Nodules: Value and Management

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Initially Nondiagnostic Ultrasound-Guided Fine-Needle Aspiration Biopsy of Thyroid Nodules: Value and Management

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The Master's Thesis submitted to the Department of Medicine, the Graduate School of Yonsei University in partial fulfillment of the requirements for the degree of Master of Medical Science

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Abstract

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I. INTRODUCTION

The management of patients with thyroid fine-needle aspiration biopsy (FNAB) specimens that are nondiagnostic cytologic results still remains problematic. Aims of this study were to investigate the incidence of thyroid cancer among the initially nondiagnostic cases of FNAB and to compare the final cytopathologic results between probably benign and suspicious nodules in ultrasonography (US) with suggesting the management of initially nondiagnostic thyroid nodules at FNABs.

II. MATERIALS AND METHODS

From July 2006 to December 2009, 10,317 thyroid nodules in 6,684 consecutive patients underwent US-guided FNAB. Among them, 871 thyroid nodules (8.4%) that were diagnosed as nondiagnostic at initial cytologic evaluation and 196 thyroid nodules underwent subsequent second or third FNAB. Twenty-seven thyroid nodules (18.9%) were underwent surgery and 116 thyroid nodules were considered as benign which were cytologically confirmed as benign and showed no remarkable change at follow-up US. US findings of total 143 thyroid nodules (123 benign nodules and 20 malignant nodules) in 138 patients (M: F = 20: 118; mean age, 50.5 years) were retrospectively reviewed. US features were including internal composition, echogenicity, margin, calcifications, shape and underlying echogenicity.

III. RESULTS

In total, thyroid cancers were diagnosed in 20 nodules (14.0%, 19 papillary carcinomas and one minimally invasive Hurthle cell cancer). Lesion size varied from 3 to 40mm (mean, 10.4mm). Fourteen lesions were palpable and the others were incidentally found. The size of lesion was significantly associated with malignancy ($P < 0.05$). Only two sonographically probable benign nodules revealed malignancy (2.4%). Suspicious nodule on US

showed thyroid cancer in 43.2%. Markedly hypoechogenicity, microlobulated or irregular margin, microcalcifications and taller-than-wide shape were significant US findings that correlated with malignancy ($P < 0.05$). Diagnostic performance of ultrasound of initially nondiagnostic thyroid nodules was calculated as follow: sensitivity 90.0%, specificity 65.0%, positive predictive value 29.5 %, and negative predictive value 97.6%.

IV. DISCUSSION

Malignancy rates of thyroid nodules which were showed non-diagnostic result in FNAB was 14.0% in our study. Considering the management of thyroid nodules with nondiagnostic FNAB cytology, the US evaluation is a feasible method and useful in predicting malignancy.

V. CONCLUSION

Although nondiagnostic cytologic result at initial FNAB, repeat FNAB is needed for sonographically suspicious nodules, due to 14% of malignancy rates in nondiagnostic thyroid nodules. However, follow-up US is more recommended rather than repeat FNAB for sonographically probably benign nodules. Sonographic findings of thyroid nodules with nondiagnostic results

at FNABs are useful method to plan the management.

Key words: thyroid nodules, fine-needle aspiration biopsy, sonography, thyroid cancer

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I. INTRODUCTION

A fine-needle aspiration biopsy (FNAB) of thyroid nodule is an accurate, reliable and minimally invasive method to identify a thyroid nodule as benign or malignant. In addition, the use of ultrasound (US) guidance can improve diagnostic accuracy and permits accurate biopsy of small nonpalpable thyroid nodules with visualization of the needle within the lesion. Nowadays, the main role of FNAB of thyroid nodule is to triage patients for either surgery or conservative management with benign, suspicious, or malignant cytologic evaluation. However, a dilemma occurs in the 10% to 21% of patients who have cytologic findings that are nondiagnostic and the current management of

nondiagnostic thyroid nodules remains controversial.[1-4] Repeat aspiration of cytology of thyroid nodules may correct initial false negative results and Chehade et al. showed a reduction in the false negative rate from 5.2% to 1.3% after a second aspiration was performed.[5] On the other hand, Shin et al reported the repeat FNA results still showed 14% of nondiagnostic cases.[6] Previous studies reported the incidence of malignancy to be 5-37% among nondiagnostic thyroid nodules.[7,8] Current opinion suggests that nondiagnostic aspirated should be repeated, however, the algorithm for managing these nondiagnostic cases has not been established.

The aims of this study were to investigate the incidence of thyroid cancer among the nondiagnostic cases of FNAB and to compare the final cytopathologic results between probably benign and suspicious nodules in US with suggesting the management of initially nondiagnostic thyroid nodules at FNABs.

II. MATERIALS AND METHODS

1. Study Population

This study was approved by the institutional review of board. Informed consent was not required for this retrospective study, however, informed consent for FNAB was obtained from all patients prior to biopsy. From July 2006 to December 2009, 10,317 focal thyroid nodules in 6684 consecutive patients underwent US-guided FNAB at Gangnam Severance Hospital (Seoul, Korea). Among them, 871 thyroid nodules (8.4%) were diagnosed as nondiagnostic at initial cytologic evaluation and 197 thyroid nodules in 190 patients were underwent subsequent second or third FNAB. Twenty-seven thyroid nodules (18.9%, 27 patients) were underwent surgery and 116 thyroid nodules were considered as benign which were cytologically confirmed as benign and showed no remarkable change at follow-up US. Remaining 53 thyroid nodules were excluded owing to a lack of further evaluation, such as surgery, follow-up FNAB, or follow-up US Finally, 143 thyroid nodules (27 surgically confirmed thyroid nodules and 116 cytologically confirmed thyroid nodules with no remarkable change on follow-up US) were included in study (Fig. 1).

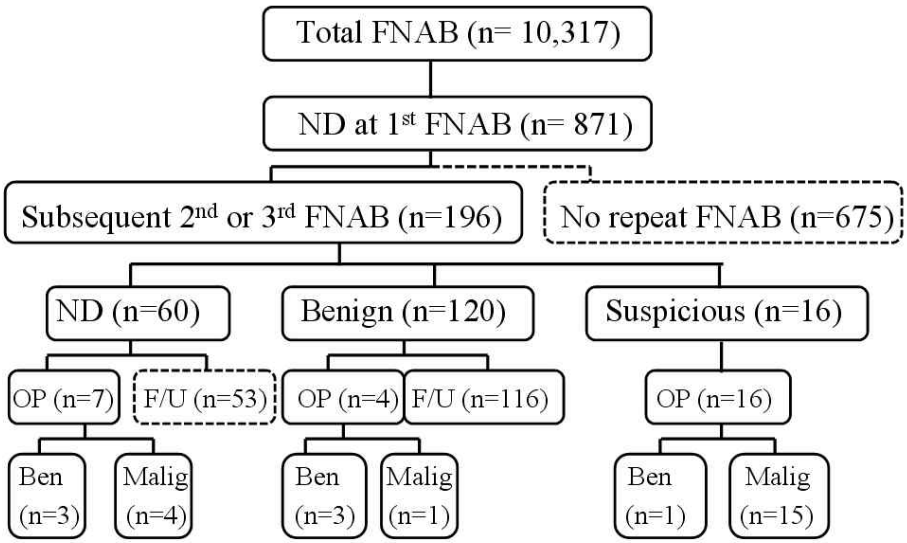


Figure 1. Summary of thyroid nodules

This study included 143 thyroid nodules in 138 patients (118 women, 20 men). Mean age of all patient was 50.5 years (range, 26 – 79 years), mean age of male patients was 49.3 years (range, 27 – 67 years), and mean age of female patients was 50.7 years (range, 26 – 79 years). The mean lesion size was 10.4 mm (range, 3 – 40 mm). Fourteen thyroid nodules were palpable and the remaining 129 thyroid nodules (90.2%) were incidentally found on the US.

2. Imaging Surveillance

Thyroid US images were obtained by using a 7- to 15-MHz linear array transducer (HDI 5000; Philips Medical Systems, Bothell, WA, USA), or a 5-

to 12-MHz linear array transducer (iU22; Philips Medical Systems) for evaluation of thyroid glands and necks. Real-time US was performed by one of three radiologists (two radiologists with more than 5 years of experience in thyroid US and one radiologist with more than 2 years of experience in thyroid US).

Ultrasonographic findings of total 143 thyroid nodules were retrospectively reviewed. The length, width, and depth of each nodule were evaluated on US images and the size was obtained at the longest aspect. The location (right and left) of each nodule was also reported. Focal thyroid nodules were interpreted by using US features, including internal compositions (solid, cyst, mixed, sponge < 50%, and sponge > 50%), echogenicity (hyper, iso, hypo, and markedly hypoehcoic), margin (circumscribed, microlobulated, and irregular), combined calcifications (micro, macro, eggshell, negative and mixed), shape (parallel and non-parallel) and underlying echogenicity (homogeneous and heterogeneous).

The final US assessment was probably benign, low suspicious and suspicious. Malignant US features were defined as markedly hypoechogenicity (decreased echogenicity compared with the surrounding strap muscle), a microlobulated (the presence of many small lobules on the surface of a nodule) or irregular margin, microcalcifications, and taller-than-wide shape (greater in the anteroposterior dimension than the transverse

dimension) on the basis of previously published criteria.[9] A low suspicious nodule (positive US feature) was defined if one of the above findings were present. Suspicious nodule was defined as thyroid nodules with two or more suspicious features on US. If a nodule showed no suspicious features, it was classified as probably benign.

3. US-guided FNAB and the Reference Standard

US-guided FNAB of thyroid nodule was performed by radiologist. FNABs were performed either for thyroid nodules with suspicious US features. In patients with more than one nodule, the most suspicious nodule was aspirated in accordance with the criteria mentioned above or the largest thyroid nodule if no suspicious US features were detected. US-guided FNAB was performed with a 23-gauge needle (Korea Vaccine, Seoul, Korea) attached to a 2-mL disposable syringe (Kovax-Syringe, Seoul, Korea) without an aspirator. Materials obtained from the aspiration biopsy were expelled on four glass slides and smeared. All smears were immediately placed in 95% alcohol for Papanicolau and hematoxylin and eosin staining. The remainder of the materials in the syringe was rinsed in saline for processing as a cell block. Additional special staining was performed on a case-by-case basis according to the cytopathologist's needs. One of three cytopathologists (over 10 years of

experience) interpreted the FNAB slides.

Specimens were considered nondiagnostic if insufficient cellular material (< 6 groups of well-preserved > 15 cells each) or predominantly of blood is present, or both colloid and follicular cells are present.

4. Statistical Analysis

We compared patients in the benign and malignant groups according to categorical variables by chi-squared test (nominal data). We also evaluated the comparison between benign and malignant groups with continuous variables by independent two-sample *t*-test. Diagnostic performance of US and the incidence of thyroid cancer among the initially nondiagnostic cases of FNAB were calculated. Statistical significance was assumed when the *P* value was < 0.05. Ninety-five percent confidence intervals were calculated for proportions based of exact binomial tables. Statistical analysis was performed with SPSS version 15.0 software (SPSS, Chicago, IL, USA).

III. RESULTS

1. Patient and Final Cytopathologic Results

A total 143 thyroid nodules of the 138 patients included in our study, 118 patients (85.5%) were female and 20 patients (14.5%) were male. The mean size of the thyroid nodule on US was 10.4 mm (range, 3 – 40 mm). Fourteen thyroid nodules (9.8%) were palpable and the others were incidentally found on US. Eighty-nine nodules (62.2%) were located in the right lobe of thyroid and 54 nodules (37.8%) were located in the left lobe of thyroid.

In total 143 nodules, thyroid cancers were diagnosed with surgery in 20 nodules (14.0%, 19 papillary carcinomas and one minimally invasive Hurthel cell cancer) and the benign was diagnosed in 123 nodules (7 nodules confirmed by means of surgery and 116 nodules confirmed by means of repeat FNAB and follow-up US). The patient demographics are listed in Table 1.

Table 1. Comparison of patient demographics with final cytopathology of 143 thyroid nodules with initially nondiagnostic fine-needle aspiration biopsy results

Characteristic	Malignant	Benign	*p-value*
Age (years) (mean)	50.7	50.4	0.453
Sex, n (%)			0.275
Male	2 (8.0)	23 (92.0)	
Female	18 (15.3)	100 (84.7)	
Lesion size (mm) (mean)	8.7	10.7	0.017
Location, *n* (%)			0.469
Right	13 (14.6)	76 (85.4)	
Left	7 (13.0)	47 (87.0)	
Symptom, *n* (%)			0.675
Palpable	1 (7.1)	13 (92.9)	
Incidental	19 (14.7)	110 (85.3)	

Malignant nodules were significantly smaller than benign nodules ($p < 0.05$). Age, sex, location of nodule and symptom were statistically insignificant.

2. US Analysis

US features of thyroid nodules are summarized in Table 2.

Table 2. Comparison of US features with cytopathology of 143 initially nondiagnostic thyroid nodules in fine-needle aspiration biopsy

US feature	Total, *n* (%) (*n* = 143)	Benign, *n* (%) (*n* = 123)	Malignant, *n* (%) (*n* = 20)	*p-value*
Composition				0.050
Solid	89 (62.2)	71 (79.1)	18 (20.9)	
Mixed	41 (28.7)	39 (91.9)	2 (8.1)	
<50% sponge	3 (2.1)	3 (2.1)	0 (97.9)	
>50% sponge	10 (7.0)	10 (7.0)	0 (93.0)	
Echogenicity				<0.001
Hyperechoic	3 (2.1)	3 (100)	0 (0)	
Isoechoic	36 (25.2)	36 (100)	0 (0)	
Hypoechoic	92 (64.3)	79 (85.9)	13 (14.1)	
Markedly hypoechoic	12 (8.4)	5 (41.7)	7 (58.3)	
Margin				<0.001
Circumscribed	93 (65.0)	89 (95.7)	4 (4.3)	
Microlobulated	34 (23.8)	26 (76.5)	8 (23.5)	
Irregular	16 (11.2)	8 (50.0)	8 (50.0)	
Calcifications				<0.001
Microcalcifications	15 (10.5)	7 (46.7)	8 (53.3)	
Macrocalcifications	20 (14.0)	18 (90.0)	2 (10.0)	
Eggshell	1 (0.7)	1 (100)	0 (0)	
Negative	105 (73.4)	96 (91.4)	9 (8.6)	
Mixed	2 (1.4)	1 (50.0)	1 (50.0)	
Shape				<0.001
Parallel	106 (74.1)	99 (93.4)	7 (6.6)	
Taller-than-wide	37 (25.9)	24 (64.9)	13 (35.1)	

Underlying echogenicity				0.69
Homogeneous	135 (94.4)	116 (85.9)	19 (14.1)	
Heterogeneous	8 (5.6)	7 (87.5)	1 (12.5)	
US assessment				<0.001
Probably benign	82 (57.3)	80 (97.6)	2 (2.4)	
Low suspicious	24 (16.8)	22 (91.7)	2 (8.3)	
Suspicious	37 (25.9)	21 (56.8)	16 (43.2)	

The most of sonographically probably benign nodules revealed benign in 97.6%. Probably benign, low suspicious and suspicious nodules on US showed thyroid cancers in 2.4%, 8.3% and 43.2%, respectively ($P < 0.05$). Markedly hypoechogenicity, microlubulated or irregular margin, microcalcifications and taller-than-wide shape were significant US findings that correlated with malignancy ($P < 0.05$). Diagnostic performance of ultrasound of initially nondiagnostic thyroid nodule was calculated as follow: sensitivity 90.0%, specificity 65.0%, positive predictive value 29.5% and negative predictive value 97.6%.

IV. DISCUSSION

US-guided FNAB of thyroid nodule is a method used worldwide to diagnose thyroid nodules but it has limitations, such as nondiagnostic results. Incidence of malignancy in thyroid nodules with nondiagnostic cytologic results showed wide range in previous studies.[6-9] Our study showed nondiagnostic results at initial FNAB with 8.4% and among them 14% of thyroid nodules were finally confirmed as malignancy. Therefore, cytologic-clinicoradiologic correlation can be important follow-up step to manage these thyroid nodules with initially nondiagnostic cytologic results. In our study, malignancy rate of thyroid nodules which were showed nondiagnostic result in FANB was 14.0% and this result was comparable with previous reports (range, 5-37%).[6-9]

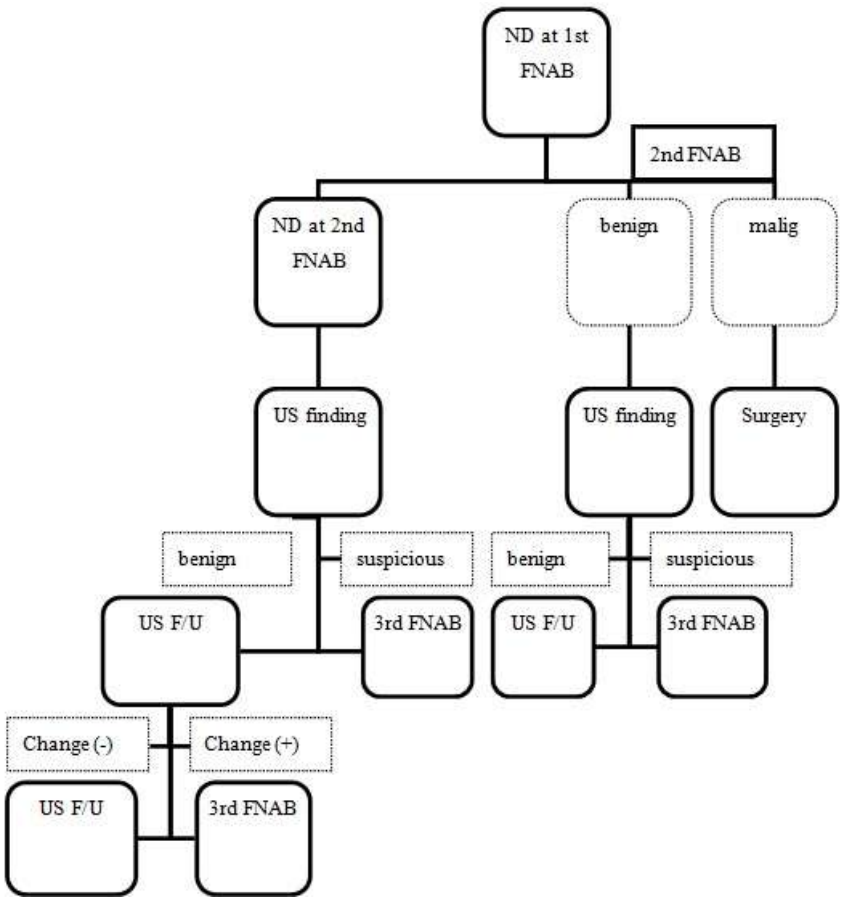
Previous studies showed the mean size of benign thyroid nodules was larger than for malignant thyroid nodules with no significant difference.[9-11] Current large studies showed the increasing rates of small thyroid cancers with advances in diagnostic techniques, such as high-resolution US and the increasing numbers of imaging studies to establish the diagnosis of thyroid cancer.[12-14] In our study, the mean size for benign thyroid nodules was larger than for malignant thyroid nodules and the size of lesion was statistically significantly associated with malignancy (the mean size: 8.7mm for malignant nodules versus 10.7mm for benign nodules, $p = 0.017$), but sex, age, location and symptom were not. This result was probably related to selective thyroid

nodules, found incidentally on screening US examination. Increasing numbers of thyroid nodules are found incidentally on head and neck ultrasounds for carotid or breast disease and CT or PET scans for metastatic surveillance.[15] The prevalence of incidental thyroid nodules on US has been found to be as high as 17 % to 67 %.[16-18] In our study, 90.2 % of thyroid nodules was found incidentally, which was more higher incidence than previously reported.

Many reports described suspicious US features, such as microlobulated or irregular margins, hypoechogenicity, microcalcifications, solid component, a taller-than-wide shape, and intratumoral vascularity.[9,19-23] In our study, we used the US classification described by Kim et al because of its simplicity and high diagnostic accuracy.[9] Our study also shows that the presence of microcalcifications, microlobulated or irregular margins, markedly hypoechogenicity, and taller-than-wide shape was statistically significantly associated with malignancy. Sonographically suspicious nodules were finally proved malignancy in 43.2% and only 2.4% in sonographically probably benign nodules revealed malignancy in our study. It suggests suspicious US features are helpful in management of thyroid nodules with initially nondiagnostic cytologic results. Thyroid nodules with nondiagnostic result in FNAB are required repeat FNAB, because its high malignancy rate, 14.0% in this study. Repeat FNAB is needed for thyroid nodules with nondiagnostic result in initial FNAB and correlations with US findings are helpful for

thyroid nodules with continuously nondiagnostic results in second or third FNAB. Follow-up US is required for sonographically probably benign nodules with nondiagnostic results in FNAB and the repeat FNAB is needed when the size or the US findings of these nodules are changed during follow-up US (Fig.2).

Figure 2. Management of thyroid nodules with nondiagnostic fine-needle aspiration biopsy results



There were several limitations to our study. First, this study was a retrospective study including patients who had more than two FNABs with surgery or follow-up US. Selection bias may have existed during the inclusion process. Second, relatively small sample size (n=143) could be limitation of our study and large sample study should be needed. Third, we regarded nodules with benign cytologic result consider as benign. Surgically confirmed cases were only 27 thyroid nodules (18.9%).

V. CONCLUSION

Considering the management of thyroid nodules with nondiagnostic FNAB cytology, the US evaluation is a feasible method and useful in predicting malignancy. Repeat FNAB is essential for nondiagnostic nodules in initial FNAB, However, the follow-up US could be feasible methods for sonographically probably benign nodules with contiguously nondiagnostic results in repeat FNAB.

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Abstract (in Korean)

갑상선 결절의 초기 비진단적 초음파 유도하 미세침흡인술 결과의 평가와 처리

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정진

I. 서론:

갑상선 미세침흡인술 결과상 비진단적인 결과가 나온 환자의 처리는 여전히 문제가 되고 있다. 본 연구의 목적은 미세침흡인술 결과상 초기에 비진단적인 결과가 나온 갑상선 결절에서 갑상선 암의 발생률과 초음파상 양성으로 생각 되어지는 경우와 초음파상 악성이 의심스러운 경우를 최종 세포병리적인 결과와 비교 연구를 하여 이러한 미세침흡인술 상 비진단적 결과가 나온 경우의 평가와 처리에 대하여 연구하고자 하였다.

II. 재료 및 방법

2006년 7월부터 2009년 12월까지 총 6684명의 환자 중 10317개의 갑상선 결절에서 초음파 유도하 미세침흡인술을 시행하였다. 그 중 871개 (8.4%) 갑상선 결절 에서 초기에 비진단적인 결과가 나왔으며 그 중 196개 갑상선 결절에서 2번 혹은 3번의 미세침흡인술을 시행을 하였다. 27개 (18.9%) 갑상선 결절이 수술로 확진이 되었으며 2번 혹은 3번 째 미세침흡인술 결과상 양성으로 확인된 후 초음파를 주기적으로 시행하여 변화가 거의 없는 116개의 갑상선 결절은 양성으로 간주를 하였다. 총 143개의 갑상선 결절 (양성 123개, 악성 20개)에 대하여 초음파 소견을 후향적으로 분석을 하였다. 초음파 소견은 내부의 성분, 에코, 경계, 석회질, 모양과 배경 에코를 분석하였다.

III. 결과

전체적으로 갑상선 암은 20개 (14.0%) 에서 진단이 되었다. 결절의 크기는 3-40 mm (평균, 10.4 mm) 였으며 14개는 만져졌으며 나머지는 우연히 발견이 되었다. 악성이 양성 결절보다 크기가 작았으며 통계적으로도 유의하였다 ($P< 0.05$). 초음파상 양성으로 생각된 대부분 결절(96.4%)은 실제로 양성이었다. 초음파상 악성이 의심스러운 결절에서 갑상선 암의

발생률은 43.2% 였으며 초음파상 양성으로 판단한 경우보다 통계적으로 유의하게 암의 확률이 높았다 ($P < 0.05$). 매우 에코가 낮은 경우, 미세소엽상 혹은 불규칙한 경계를 갖는 경우, 미세석회질이 있는 경우, 혹은 폭보다 키가 큰 경우가 통계적으로 악성과 관련이 높은 초음파 소견으로 나타났다 ($P < 0.05$). 초기에 비진단적 미세침흡인술 결과가 나온 경우에서 초음파의 진단적 성과는 다음과 같다; 민감도 90.0%, 특이도 65.0%, 양성 예측도 29.5%, 그리고 음성 예측도 97.6 %.

IV. 고찰

비진단적 미세침흡인술 결과가 나온 갑상선 결절의 악성 빈도는 14.0% 였다. 본 연구는 이와 같은 비진단적 미세침흡인술 결과가 나온 갑상선 결절에서 초음파상 악성이 의심되는 소견들이 진료 방향을 정하는 데 도움을 준다는 것을 보여주었으며 초음파상 악성이 의심되는 경우에는 미세침흡인술을 재시행하고 양성이 의심스런운 경우에는 미세침흡인술을 다시 시행하기보다는 초음파로 주기적으로 지켜보는 것이 도움이 되는 것으로 나타났다.

V. 결론

비진단적 미세침흡인술 결과가 나온 갑상선 결절의 처리에 있어서 초음파는 매우 유용하며 악성을 예측하는 데 도움이 될 것이다.

핵심되는 말: 갑상선 결절, 미세침흡인술, 초음파, 갑상선암