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HEAD AND NECK

Comparison of core-needle biopsy and repeat fine-needle aspiration for thyroid nodules with inconclusive initial cytology

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Abstract

Purpose We aimed to compare the efficacy of ultrasound-guided core-needle biopsy (CNB) with repeat fine-needle aspiration (rFNA) cytology in thyroid nodules with inconclusive results in initial fine-needle aspiration cytology.

Methods We studied 402 patients who required a repeat biopsy of thyroid nodules using ultrasound-guided CNB ($n=192$) or rFNA ($n=210$) because of inconclusive results in initial FNA, corresponding to categories I, III, and IV of the Bethesda System for Reporting Thyroid Cytopathology. If repeat biopsy results were benign (category II), suspicious malignancy (category V), or malignancy (category VI), they were defined as "diagnostic results". The diagnostic yield and performances of repeat biopsy were analyzed and compared between the rFNA and CNB groups.

Results The diagnostic results were obtained significantly higher in the CNB group than in the rFNA group (72.4% vs. 52.4%; $P<0.001$). In the subgroup analysis, the diagnostic results were significantly higher in the CNB group than in the rFNA group for patients of categories I and III ($P<0.001$ in both) in initial FNA. However, in patients with category IV nodules, there were no significant differences in diagnostic results between the two groups ($P=0.46$).

Conclusion Compared to rFNA, ultrasound-guided CNB is useful and effective as a repeat biopsy option for thyroid nodules with non-diagnostic results (category I) and atypia of undetermined significance (AUS) or follicular lesion of undetermined significance (FLUS) (category III) in initial FNA.

Keywords Core-needle biopsy · Fine-needle aspiration · Thyroid nodule · Thyroid cancer

Introduction

Thyroid nodules are common problems, frequently encountered in clinical practice. The prevalence of thyroid nodules is about 10–70% in the general population and is higher in females and the elderly [1, 2]. With advancements in imaging technologies including ultrasonography (US), the detection rate of thyroid nodules has extensively increased. Therefore, accurate diagnosis of thyroid nodules and their proper management by optimal therapeutic approaches have gained considerable importance [3]. Cytological evaluation of thyroid nodules with ultrasound-guided fine-needle aspiration (FNA) is the standard diagnostic tool owing to its cost-effectiveness, simplicity, safety, and diagnostic accuracy [4, 5]. However, it has several limitations, such as false-negative results and a relatively high incidence of non-diagnostic or indeterminate results, corresponding to categories I, III, and IV of the Bethesda System for Reporting Thyroid Cytopathology (TBSRTC) [3, 6, 7].

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Non-diagnostic results that are categorized as "category I" in TBSRTC are reported with a rate of 5–20% in FNA cytology [8, 9]. The American Thyroid Association (ATA) guidelines recommended a repeat FNA (rFNA) for thyroid nodules with category I result in initial FNA [3]; however, the rate of non-diagnostic results reported with rFNA cytology is still high, ranging up to 50% [10, 11]. Furthermore, the incidence of atypia of undetermined significance (AUS) or follicular lesion of undetermined significance (FLUS) (category III) is reported to be about 1–27% with FNA [12, 13], and the ATA guidelines recommend rFNA or molecular testing for such nodules [3]. However, 10–30% of category III nodules are rediagnosed as category III in the rFNA [14–16].

Therefore, other diagnostic tools were needed to overcome the limitations of rFNA for a conclusive diagnosis of thyroid nodules with initial non-diagnostic or inconclusive results. Several studies have suggested the use of core-needle biopsy (CNB) as an alternative tool to FNA for the diagnosis of thyroid nodules. Recent studies have demonstrated that compared to rFNA, CNB has a significantly lower rate of inconclusive results in the secondary diagnostic biopsy of thyroid nodules after non-diagnostic results are revealed by initial FNA cytology [4, 17, 18]. The Korean Society of Thyroid Radiology recommends considering CNB as an alternative to rFNA for thyroid nodules with previous non-diagnostic or inconclusive FNA cytology [4, 17]. However, in some studies, CNB did not show better diagnostic results than FNA [19, 20]. Furthermore, it is argued that the potential risk of complications with CNB is higher than that with FNA [21, 22].

The efficacy of CNB as an alternative to rFNA in cases with inconclusive or non-diagnostic initial FNA has not been well explored. Therefore, this study aimed to investigate the efficacy and role of CNB in comparison to that of rFNA cytology for thyroid nodules with inconclusive or non-diagnostic initial FNA cytology.

Methods

Patients

The study retrospectively reviewed medical records of 402 patients with thyroid nodules who underwent ultrasound-guided rFNA or CNB for repeat biopsy because of inconclusive results in initial FNA corresponding to categories I, III, and IV of TBSRTC from January 2011 to December 2017 in Hanyang University Hospital. We divided the patients into the rFNA group ($n = 210$) or the CNB group ($n = 192$), respectively. The study excluded patients who underwent FNA ≥ 2 times prior to the repeat biopsy or who underwent initial FNA at another hospital. The study protocol was approved by the Institutional Review Board of Hanyang University Hospital.

FNA and CNB procedures

Ultrasound-guided repeat biopsies were conducted by two experienced radiology specialists (JSP and HRK) using either US equipment—iU22 color Doppler unit (Philips Healthcare, Bothell, WA, USA) or Aixplorer color Doppler (Supersonic Imagine, Aix-en-Provence, France). Repeat biopsy was performed on the same thyroid nodule as in the initial FNA.

For FNA cytology, a 21–25-gauge needle was primarily used, but the needle size was changed depending on the nodule characteristics. FNA was performed 1–2 times on each nodule, and the aspirated material was immediately smeared on the slides and fixed with 95% alcohol. The performers assessed specimens' adequacy in the smear slides.

For CNB, an 18-gauge, double-action spring-activated biopsy needle (TSK Stericut; Create Medic, Yokohama, Japan) was used. Local anesthesia was administered at the puncture site with 1% lidocaine, following which the biopsy needle was placed in the solid portion of the nodule, and CNB procedure was performed after reconfirming that the surrounding vessels were not damaged. The obtained tissue core was immediately fixed with 10% buffered formalin.

Pathologic analysis

The FNA slides and CNB tissues were interpreted by experienced pathologists. FNA cytology and CNB histology findings were classified according to TBSRTC into six categories—non-diagnostic or unsatisfactory (category I), benign (category II), AUS or FLUS (category III), follicular neoplasm (FN) or suspicious for follicular neoplasm (SFN) (category IV), suspicious for malignancy (category V), and malignant (category VI) [23, 24].

If repeat biopsy findings were found to be benign (category II), suspicious malignancy (category V), or malignancy (category VI), they were defined as "diagnostic results"; however, if the repeat biopsy findings indicated categories I, III, and IV, they were defined as "inconclusive results."

Diagnostic performances of repeat biopsy

To determine the accuracy of rFNA and CNB for diagnosing malignancy, the repeat biopsy results were compared with the final diagnosis in each same nodule. The final diagnosis was considered to be obtained in the following three circumstances: the final pathologic result was obtained after surgery; the same result (categories II, V, and VI) was obtained in repeat biopsy (either FNA or CNB) within 6 months among patients who did not undergo surgery; and in case of

benign nodules (category II) without surgery, if there was no change observed in size or characteristic of nodules according to K-TIRADS (Korean Thyroid Imaging Reporting and Data System) even after US follow-up for > 2 years [25]. Among 402 patients, 232 (57.7%) patients from the rFNA group ($n = 97$) and the CNB group ($n = 135$) received the final diagnosis based on the abovementioned criteria. Of 232 patients with the final diagnosis, the diagnostic accuracy, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of diagnosing malignancy were calculated in each group.

Statistical analysis was performed using the SPSS version 24 program (IBM, Armonk, NY). The parameters were compared using Pearson's chi-square test, and P values of < 0.05 and < 0.001 were considered as statistically significant and highly statistically significant, respectively.

Results

There were no significant differences in demographics of the patients between the rFNA and CNB groups. The distribution of initial FNA cytology were non-diagnostic or unsatisfactory ($n = 150$; 37.3%), AUS/FLUS ($n = 192$; 47.8%), and FN/SFN ($n = 60$; 14.9%) (Table 1).

Results of repeat biopsy

The distribution of repeat biopsy results according to initial cytologic categories are shown in Table 2. The diagnostic results were obtained in 249 (61.9%) of 402 patients. Of the total 402 patients, the rate of the diagnostic result was significantly higher in the CNB group than in the rFNA group (72.4% vs. 52.4%; $P < 0.001$). In particular, non-diagnostic or unsatisfactory (category I) results were lower in the CNB group than that in the rFNA group (1.6% vs. 23.3%).

Table 1 Demographics of patients who underwent repeat fine-needle aspiration (rFNA) or core needle biopsy (CNB)[a]

Characteristics	Total ($n = 402$)	rFNA ($n = 210$)	CNB ($n = 192$)	P value
Demographics				
Age,[b] years	56 ± 13	58 ± 13	54 ± 13	0.671
Sex (Female)	316 (78.6%)	166 (79.0%)	150 (78.1%)	0.822
Initial FNA results				
Category I	150 (37.3%)	97 (46.2%)	53 (27.6%)	< 0.001
Category III	192 (47.8%)	89 (42.4%)	103 (53.7%)	
Category IV	60 (14.9%)	24 (11.4%)	36 (18.7%)	

rFNA repeat fine-needle aspiration, *CNB* core needle biopsy

[a]Values are presented as *n* (%) unless noted otherwise

[b]Expressed as Mean ± Standard Deviation

The diagnostic results obtained in the rFNA and CNB groups were compared in the three categories (I, III, and IV) of initial FNA cytology. Diagnostic results were obtained significantly higher in the CNB group than in the rFNA groups for patients of categories I (51.6% and 81.1% in the rFNA and CNB groups, respectively, $P < 0.001$) and III (57.3% and 76.7% in the rFNA and CNB groups, respectively, $P < 0.001$) in initial FNA. Also, non-diagnostic or unsatisfactory (category I) results were lower in the CNB group than that in the rFNA group in patients with categories of I and III. However, in patients with category IV nodules in initial FNA, the diagnostic results were obtained in 37.5% and 47.2% of the rFNA and CNB groups, respectively ($P = 0.46$).

Comparing the repeat biopsy results to the final diagnosis

To analyze the diagnostic performances of repeat biopsy for malignancy, we compared the results of repeat biopsy to the final diagnosis (Table 3). The final diagnosis was obtained in 97 and 135 patients in the rFNA group and the CNB group, respectively. Ninety-one patients (rFNA group, $n = 34$; CNB group, $n = 57$) underwent surgery and obtained the final diagnosis, and 7 patients (rFNA group, $n = 4$; CNB group, $n = 3$) underwent repeat biopsy again and obtained the final diagnosis. A total of 134 patients with benign results (rFNA group, $n = 59$; CNB group, $n = 75$) obtained the final diagnosis after US follow-up for more than 2 years; and there was no change of nodule characteristics.

Of 13 patients who obtained category V and VI results on rFNA, 1 (7.7%) patient was found to have a benign nodule and the remaining were found to have malignant nodules in the final diagnosis. Among all the 19 patients who obtained categories V and VI results on CNB, malignancy was reported in the final diagnosis (Table 3).

The diagnostic accuracy, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) are shown in Table 4. The diagnostic accuracy was found to be 89.7% and 87.4% in the rFNA and CNB groups, respectively. The sensitivity was 57.1% and 52.8 in the rFNA and CNB groups, respectively; the specificity was 97.7% and 100% in the rFNA and CNB groups, respectively.

Complications

No significant complications, such as infection, severe hematoma, nerve injury, or seeding of the tumor, were reported in either group, except 2 cases of minor bleeding. Minor subcapsular hematoma occurred in 1 case in the rFNA group, and skin ecchymosis and bruise occurred in 1 case in the CNB group.

Table 2 Results of repeat biopsy according to the initial fine-needle aspiration cytology[a]

Initial FNA		Repeat biopsy		*P* value
		rFNA ($n=210$)	CNB ($n=192$)	
Category I; Non-diagnostic or unsatisfactory ($n=150$)	Inconclusive results[b]	47 (48.5%)	10 (18.9%)	< 0.001
	Diagnostic results[c]	50 (51.5%)	43 (81.1%)	
	Category I	35 (36.1%)	2 (3.8%)	
	Category II	44 (45.4%)	37 (69.8%)	
	Category III	9 (9.3%)	0 (0%)	
	Category IV	3 (3.1%)	8 (15.1%)	
	Category V	4 (4.1%)	3 (1.6%)	
	Category VI	2 (2.1%)	3 (1.6%)	
Category III; Atypia/follicular lesion of undetermined significance ($n=192$)	Inconclusive results	38 (42.7%)	24 (23.3%)	< 0.001
	Diagnostic results	51 (57.3%)	79 (76.7%)	
	Category I	11 (12.4%)	1 (1%)	
	Category II	40 (44.9%)	59 (57.3%)	
	Category III	20 (22.5%)	0 (0%)	
	Category IV	7 (7.9%)	23 (22.3%)	
	Category V	8 (9.0%)	14 (13.6%)	
	Category VI	3 (3.4%)	6 (5.8%)	
Category IV; Follicular neoplasm or suspicious for follicular neoplasm ($n=60$)	Inconclusive results	15 (62.5%)	19 (52.8%)	0.457
	Diagnostic results	9 (37.5%)	17 (47.2%)	
	Category I	3 (12.5%)	0 (0%)	
	Category II	7 (29.2%)	17 (47.2%)	
	Category III	3 (12.5%)	0 (0%)	
	Category IV	9 (37.5%)	19 (52.8%)	
	Category V	2 (8.3%)	0 (0%)	
	Category VI	0 (0%)	0 (0%)	
Total ($n=402$)	Inconclusive results	100 (47.6%)	53 (27.6%)	< 0.001
	Diagnostic results	110 (52.4%)	139 (72.4%)	
	Category I	49 (23.3%)	3 (1.6%)	
	Category II	91 (43.3%)	113 (58.9%)	
	Category III	32 (15.2%)	0 (0%)	
	Category IV	19 (9.1%)	50 (26.0%)	
	Category V	14 (6.7%)	17 (8.9%)	
	Category VI	5 (2.4%)	9 (4.7%)	

rFNA repeat fine-needle aspiration, *CNB* core needle biopsy, *n.d.* not determinable

[a]Values are presented as *n* (%) unless noted otherwise

[b]Inconclusive results included categories I, III, and IV

[c]Diagnostic results included categories II, IV, and VI

Discussion

Ultrasound-guided FNA cytology is considered a key investigation in the management of thyroid nodules; however, rFNA is recommended for nodules with non-diagnostic or inconclusive results in initial FNA to avoid unnecessary diagnostic surgery [1, 3, 9, 26]. Nevertheless, the inconclusive or non-diagnostic result rates of rFNA have been persistently reported as 20–36% [9, 14, 27]. Ultrasound-guided CNB is suggested as an alternative and complementary tool to rFNA owing to its safety and accuracy [18, 20, 28]. CNB has some potential advantages over FNA; it allows the collection of a significant amount of tissue from the lesion, thus providing more information about the histologic architectural structure and allowing immunochemical staining [4].

Table 3 Comparison of the final diagnosis and repeat biopsy results

Repeat biopsy results	Repeat biopsy methods		Final diagnosis
	rFNA[a] ($n=97$)	CNB[a] ($n=135$)	
Category I ($n=19$)	15 (88.2%)	1 (50%)	Benign ($n=16$)
	2 (11.8%)	1 (50%)	Malignancy ($n=3$)
Category II ($n=116$)	39 (97.5%)	74 (97.4%)	Benign ($n=113$)
	1 (2.5%)	2 (2.6%)	Malignancy ($n=3$)
Category III ($n=19$)	14 (73.7%)	0 (0%)	Benign ($n=14$)
	5 (26.3%)	0 (0%)	Malignancy ($n=5$)
Category IV ($n=46$)	7 (87.5%)	24 (63.2%)	Benign ($n=31$)
	1 (12.5%)	14 (36.8%)	Malignancy ($n=15$)
Category V ($n=20$)	1 (11.1%)	0 (0%)	Benign ($n=1$)
	8 (88.9%)	11 (100%)	Malignancy ($n=19$)
Category VI ($n=12$)	0 (0%)	0 (0%)	Benign ($n=0$)
	4 (100%)	8 (100%)	Malignancy ($n=12$)

rFNA repeat fine-needle aspiration, *CNB* core needle biopsy

[a]Values are presented as *n* (%)

Table 4 Diagnostic performances of repeat fine-needle aspiration and core needle biopsy

	rFNA	CNB
Diagnostic accuracy[a]	89.7	87.4
Sensitivity[a]	57.1	52.8
Specificity[a]	97.7	100
Positive predictive value[a]	92.3	100
Negative predictive value[a]	89.3	85.3

rFNA repeat fine-needle aspiration, *CNB* core-needle biopsy

[a]Values are presented as percentage

In this study, the CNB group achieved significantly higher diagnostic results than the rFNA group (72.4% vs. 52.4%, $P<0.001$) and the CNB group showed significantly lower rates of non-diagnostic (category I) results than the rFNA group. Among the patients ($n=192$) in the CNB group, only 3 patients (1.6%) obtained a category I result, whereas, among the patients ($n=210$) in the rFNA group, 49 patients (23.3%) obtained a category I result. According to the ATA guidelines, diagnostic surgery is advocated in these 52 patients with category I results. Moreover, the CNB group not only revealed lower rates of non-diagnostic or unsatisfactory (category I) results in the total patients but also in each individual subgroup of categories I, III, and IV. Particularly, among patients who had a category, I result in initial FNA, 35 patients (36.1%) were found to have the same category I result in rFNA. However, in the CNB group, only 2 cases (3.77%) were found to have a category I result. In the cases with categories III and IV in initial FNA, the non-diagnostic results were also lower in the CNB group than in the rFNA group. These results, therefore, suggest that compared to rFNA, CNB can substantially help reduce the reporting of non-diagnostic results and avoid the conduct of unnecessary diagnostic surgeries.

Previous studies have investigated patients with initially non-diagnostic (category I) FNA results [10, 11, 17]; however, this study included patients with categories III and IV nodules in addition to the patients with category I nodules. Among patients with initial AUS/FLUS cytology (category III) results, the diagnostic results were obtained significantly higher in the CNB group than those in the rFNA group. However, analysis of the subgroup of initial category IV FNA results (FN/SFN) revealed that the diagnostic results were relatively low in repeat biopsy using either CNB or rFNA (47.2% and 37.5% in the CNB and rFNA groups, respectively, $P=0.457$). These results suggest that a repeat biopsy using either CNB and rFNA is not effective in cases with initial category IV FNA cytology; it could be supporting evidence for the ATA guidelines that recommend diagnostic surgical excision as the long-established standard of care for the management of category IV thyroid nodules [3].

In terms of diagnostic accuracy for malignancy, some studies have demonstrated that the diagnostic accuracy of CNB is better than that of rFNA [28–31]; however, other studies have shown that there were no benefits in performing CNB [19, 20]. This study reported no major difference between the diagnostic accuracy of rFNA (89.7%) and CNB (87.4%); however, the specificity and PPV with CNB were 100%.

The complication rate was low in this study. There was only 1 case of minor bleeding in each group. In this study, two expert radiologists performed all procedures of repeat FNA and CNB. To avoid hematoma formation, we stopped any anticoagulant one week before the procedure and served pressure dressing after the procedure. Also, an

ultrasonographic evaluation was performed to check any bleeding or hematoma after the procedure.

Limitations of this study

There were some limitations to the study. The study is a retrospective, non-randomized study; therefore, it has inevitable selection bias that could have affected the study results. Moreover, it is complicated to analyze the exact diagnostic accuracy for malignancy because all enrolled patients did not undergo diagnostic surgery for confirmation of the final diagnosis.

Conclusions

Compared to rFNA, ultrasound-guided CNB is useful and effective for thyroid nodules with inconclusive results in initial FNA. It can be considered a repeat biopsy option in thyroid nodules with non-diagnostic results (category I) and AUS/FLUS cytology (category III) in initial FNA. However, a repeat biopsy using either CNB and rFNA is not effective in cases with initial category IV cytology. Further large, randomized, prospective studies are warranted to verify the study results.

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Compliance with ethical standards

Conflict of interest The authors have no conflict of interest pertaining to this manuscript.

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