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Thyroid fine needle aspiration biopsy: Do we really need an on-site cytopathologist?

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ABSTRACT

Purpose: The aim of this single center study is to evaluate the effectiveness of performing ultrasound-guided thyroid fine-needle aspiration biopsies (FNAB) performed by the radiologist alone without an on-site cytopathologist.
Materials and methods: In this prospective randomized study, 203 patients with single nodules measuring 10 mm or more underwent ultrasound-guided FNAB: 102 patients underwent FNAB performed by the radiologist accompanied by a cytopathologist (control group); 101 patients underwent FNAB by the radiologist alone (study group). In both groups biopsy time, specimen adequacy ratio, total aspiration number, cytopathologist's cytological diagnosis time (t1), cytopathologist's total time consumption (t2) were evaluated.
Results: Mean total biopsy time was 8.74 ± 2.31 min in the study group and was significantly shorter than the control group's 11.97 ± 6.75 min ($p = 0.004$). The average number of aspirations per patient in the study group was 4.00 ± 0; compared to the control group's 3.56 ± 1.23 this was significantly higher ($p = 0.001$). t1 of the study group was 307.48 ± 226.32 s; compared to 350.14 ± 247.64 s in the control group, there was no statistically significant difference ($p = 0.137$). t2 of the study group was 672.93 ± 270.45 s; compared to the control group (707.03 ± 258.78 s) there was no statistically significant difference ($p = 0.360$). Diagnostic adequacy of aspirated specimens was reassessed in the pathology laboratory. In the study group, 84 out of 101 aspirations and in the control group 89 out of 102 aspirations was determined as adequate with no statistically significant difference ($p = 0.302$).
Conclusions: We believe that in centers where a cytopathologist is not available, ultrasound-guided thyroid FNAB can be adequately performed by an experienced radiologist who was effectively trained in smear preparation.

1. Purpose

Thyroid nodules are very common, being diagnosed in 4–8% of the adult population with palpation and in 10–41% with ultrasound (US) [1–5]. In autopsy series, thyroid nodules are encountered with a prevalance of 50% [6]. When a thyroid nodule is detected, imaging alone is not enough to determine if the nodule is benign or malignant. At present, thyroid fine-needle aspiration biopsy (FNAB) is the least invasive, most accurate method to determine high-risk or malignant lesions and is thus most effective [7–9]. Thyroid FNAB is performed with or without the guidance of an US for palpable nodules and with the guidance of an US for non-palpable nodules.

In our institution thyroid FNAB is done by a radiologist with US guidance. A cytopathologist accompanies the radiologist during the procedure. The radiologist obtains the fine needle aspiration material from the nodule, while the cytopathologist spreads the sample and determines if the specimen is adequate for cytological diagnosis. In this single center study, we aim to evaluate the difference in the adequacy and the diagnostic process between thyroid FNAB performed by a radiologist with and without an on-site cytopathologist.

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2. Materials and methods

Two hundred and three patients with nodules of 10 mm and larger were included in this prospective randomized study between January 2008 and May 2010. Pure cystic nodules were excluded from the study. The patients were enrolled in the study in accordance with the "Management Guidelines for Patients with Thyroid Nodules and Differentiated Thyroid Cancer" of the American Thyroid Association Guidelines Taskforce [10]. US guided FNAB was performed for all 203 patients by a single radiologist with 1 year of experience in thyroid FNAB. The radiologist received basic training in cytopreparation from a pathologist. All biopsies were performed by the same radiologist under US guidance (Accuson Antares, Siemens, Germany) using a linear 9–12 Mhz probe and 22G aspiration needles. The patients were randomized using random permutated blocks and Zelen's design. One hundred and two patients underwent FNAB performed by the radiologist accompanied by a cytopathologist for on-site evaluation of adequacy (control group), and 101 patients underwent FNAB in the absence of the cytopathologist (study group).

In accordance with institutional ethical committee guidelines informed consent was obtained from every patient. The same biopsy technique was used for all cases; the patient lying in supine position on the examination table, a rolled towel was put under the neck to provide hyperextension. Before the biopsy, the nodule was localized with the US probe and a topical lidocaine ointment was salved on the skin at the level of the nodule. After allowing appropriate time for the anesthetic to take effect; the skin was cleansed with iodine solution. For every single aspiration a new 22G needle was used and aspiration was performed by free-hand technique under sonographic guidance. The needle tip was placed inside the nodule. During the procedure, curettage was performed before applying negative pressure. The curettage and the aspiration were continued until the aspiration material and a small amount of blood were observed at the hub of the syringe. After each aspiration, the aspirated material was sprayed on 4 different slides. The slides were overlapped onto one another, spreading the cells without smashing, and were gently pulled away from each other. The smears were fixed in 95% ethanol solution. The remaining material in every aspiration syringe was washed with Cytospin collection fluid (Shandon, Thermoscientific, USA) for building a cell block in the pathology lab. Four samples per patient were taken from each nodule in the study group and cytologic slides were prepared by the radiologist.

In the control group, the same procedure was performed with the exception that one of the four slides prepared in every aspiration was stained by the cytopathologist using a rapid toluidine blue solution and examined under the microscope to determine the diagnostic adequacy of the specimen. In the control group this procedure was continued until the cytopathologist declared that the cytological material was adequate and the total number of aspirations was noted.

Total biopsy time was noted in both groups. Biopsy time is defined as the interval that begins with the first placement of the needle inside the nodule in both groups and ends at the time when the last prepared slide was fixed in ethanol by the radiologist (study group) or at the time when the cytopathologist declared that the aspirated material was adequate for histologic diagnosis (control group). All obtained material was sent to the pathology laboratory. A total of 808 slides in the study group and 712 slides in the control group were obtained. In the pathology laboratory slides were stained with Papanicolaou dye. In both groups, the specimens were evaluated for adequacy and a final diagnosis was made by the same blinded cytopathologist who has more than 15 years of experience. In both groups, cytological diagnosis time and the cytopathologist's total time consumption in the laboratory were also noted.

Table 1
The comparison of total biopsy times, cytopathologist's definitive cytological diagnosis time (t1) and cytopathologist's total time consumption for reviewing all specimens (t2) in the study and the control groups.

	Study group	Control group	*p* Value
Patients (*n*)	101	102	
Total biopsy times (min)	8.74 ± 2.31	11.97 ± 6.75	.004
t1 (s)	307.48 ± 226.32	350.14 ± 247.64	.137
t2 (s)	672.93 ± 270.45	707.03 ± 258.78	.360

Although a definitive diagnosis can be made by the cytopathologist even after examining a single specimen, all the slides from all specimens are reviewed by the cytopathologist. Thus the diagnosis time (coined as t1) and the time required for reviewing all specimens (coined as t2) may be different from one another.

There are various proposed adequacy criteria for thyroid FNAB [11,12]. In this study, we used criteria established by Kini for evaluating the adequacy of thyroid FNAB specimens [11].

Number of total aspirations and the cytopathologist's total time consumption in the laboratory showed normal distribution and were analyzed with the Student *t*-test. Biopsy times and cytological diagnosis times did not show normal distribution and thus were analyzed with Mann–Whitney *U* test. The specimen adequacy ratio was analyzed with Pearson Chi-square test. A *p* value of 0.05 or less was accepted as statistically significant. Cytological adequacy was classified according to the criteria suggested by Kini et al. [11]. Cytological diagnosis was classified according to the Bethesda system (National Cancer Institute, Fourth Thyroid FNAB Guideline Committee) into 6 groups [12].

3. Results

One hundred and one patients, 81 female and 20 male (ages 20–83, mean 49), with single nodule underwent aspiration in the study group. One hundred and two patients, 85 female and 17 male (ages 23–86, mean 50), with single nodule were sampled in the control group.

Mean total biopsy time in the study group was significantly shorter than the mean total biopsy time of the control group (8.74 ± 2.31 vs. 11.97 ± 6.75 min respectively; $p = 0.004$) (Table 1).

The average number of aspirations in the control group was significantly less than that of the study group (3.56 ± 1.23 vs. 4.00 ± 0 aspirations per patient; $p = 0.001$) (Table 2).

The cytopathologist's definitive cytological diagnosis time in the pathology laboratory (t1) was not significantly different between control and study groups (350.14 ± 247.64 vs. 307.48 ± 226.32 s respectively; $p = 0.137$) (Table 1).

The cytopathologist's total time consumption for reviewing all specimens in the pathology laboratory (t2) did not show statistically significant difference between control and study groups (707.03 ± 258.78 vs. 672.93 ± 270.45 s; $p = 0.360$) (Table 1).

The diagnostic adequacy of aspirated specimens, which was assessed by the cytopathologist, did not show a statistically significant difference among the study and control groups (83.2% vs. 87.9%; $p = 0.302$) (Table 3).

Table 2
The comparison of biopsy aspiration numbers in the study and the control groups.

	Patient number	Average number of aspirations per patient	Standard deviation	*p* Value
Study group	101	4.00	0.00	.001
Control group	102	3.55	1.23	.001