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ORIGINAL ARTICLE

The contribution of vacuum-assisted modified Menghini type needle to diagnosis of US-guided fine needle aspiration biopsy of the thyroid

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PURPOSE
We aimed to determine the contribution of vacuum-assisted modified Menghini type needle to diagnosis of ultrasound-guided fine needle aspiration biopsy (FNAB) of the thyroid evaluated by a pathologist at the bedside.

METHODS
A total of 147 thyroid nodules in 138 patients (122 women, 16 men) were included in this prospective study. Sonographic features of nodules, number of aspirations, pain and pain severity during the process, hemorrhage, and presence of sample obtained for cell block analysis were recorded and analyzed with the results of aspiration biopsy.

RESULTS
Using the 21G modified Menghini type needle, a diagnosis could not be reached in 14.3% of nodules. Adequate samples for cell block analysis were obtained in 47 nodules (32%), 17 of which contributed to the diagnosis. While the difference between diagnostic cytopathology results and the contribution of the cell block were statistically significant, obtainability of cell block samples was not significantly correlated with the number of aspirations or the presence of a cystic component in the nodule.

CONCLUSION
FNAB with 21G vacuum-assisted modified Menghini type needle is a safe procedure with very low complication rates. In addition to the cytologic smear samples, microtissue fragments obtained with this method help pathologists in the diagnosis of thyroid nodules.

Thyroid gland nodules are common findings and palpable nodule prevalence is reported as 3%–7% in the literature (1–3). Nonpalpable thyroid nodules that cannot be detected clinically are seen on ultrasonography (US) in 13%–50% of the population (4). The most important issue in detection of a nodule is how to distinguish between benign and malignant nodules, so that unnecessary surgical procedures on benign nodules can be prevented and surgical removal of malignant nodules can be ensured.

Fine needle aspiration biopsy (FNAB) is a minimally invasive and safe diagnostic method to distinguish benign and malignant thyroid nodules, especially when performed under US guidance. The diagnostic accuracy of FNAB in experienced centers is very high; the sensitivity and specificity were reported to be approximately 85% and 99%, respectively (5).

According to the literature, FNAB may provide insufficient results in 2%–20% of the nodules (average 15%) based on whether it has been performed under US guidance or not (3). In addition to operator experience, lesion characteristics, lesion and needle localization, guiding method, number of aspirations, needle size, aspiration technique, and accompanying pathologist are among the factors affecting the results of FNAB (6). An insufficient FNAB cytology result leads to a waste of time not only for patients, but also for clinicians, radiologists, and pathologists. Moreover, repeated biopsy procedures increase the cost and the patient anxiety.

In this prospective study, we aimed to determine the contribution of 21G vacuum-assisted modified Menghini type needle to diagnosis of US-guided FNAB of the thyroid evaluated by a pathologist at the bedside. Additionally, we aimed to investigate the effect of the needle on patient comfort and examine the relation between the number of aspirations, nodule characteristics, and sufficient material obtainability.

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Methods

Patients

A total of 138 patients, 122 women (88.4%) and 16 men (11.6%), were included in this study from April 2014 to August 2014. US-guided FNAB was performed on 147 nodules. The mean age of the patients was 49.4±13.5 years (range, 18–88 years). Our study was approved by the Institutional Review Board.

Technique

In this study, 21G 10 cm modified Menghini type needle (Sono-Cut, Geotek® Medical) was used for cytologic and histologic biopsy sampling. The needle has a Menghini-type cannula and trocar point stylet, which is combined with a 10 mL syringe. By the help of a spring mechanism, the syringe plunger, which is connected to the stylet, can be charged and released automatically.

Biopsy procedure was performed by a single radiologist with five years of experience under the guidance of Logiq® S6 US device (GE Healthcare) using a linear probe (10 L, 3.5–9.5 MHz). Freehand technique was used for biopsies and 6–8 seconds of aspiration was applied during aspiration biopsies. For patient comfort, 1–2 mL subcutaneous anesthetic injection (Citanest®, %2 prilocaine hydrochloride, Astra Zeneca) was administered before needle insertion.

Smears were prepared by the pathologist accompanying the biopsy procedure and air dried. If present on the slide, microtissue fragments were collected with the help of the needle tip and placed into 10% buffered formalin to prepare the cell block. One of the smear samples was stained with Diff-Quick, for bedside assessment of sample adequacy. Steps were repeated until adequacy criteria were met. Considering time constraints and patient compliance, a maximum of three aspirations was planned for each nodule. Biopsy process was terminated before reaching the maximum number of aspiration in some patients due to various reasons like cystic dominant nodules, difficulty in localizing nodules, small nodules, and noncompliant patients .

Sonographic features of the nodules, number of aspirations, pain and pain severity during the process, hemorrhage, and the presence of samples for cell block analysis were recorded and analyzed with the results of aspiration biopsy.

Main points

- An insufficient FNAB cytology result leads to a waste of time not only for patients, but also for clinicians, radiologists, and pathologists. Moreover, repeated biopsy procedures increase the cost and the patient anxiety.
- Fine needle aspiration biopsy with 21G vacuum-assisted modified Menghini type needle is a safe procedure with very low complication rates, and it is comfortable for both patient and practitioner when used under local anesthesia and US guidance.
- Cell block obtainability is the most important advantage of this needle independently of the number of aspirations and the presence of a cystic component.
- Cell block cytology shows the structural details of the thyroid lesions very well and is useful in distinction of benign and malignant thyroid nodules with the help of immunohistochemical staining.

Table 1. Nodule characteristics

Sonographic features suspicious for malignancy	Total n=147	Benign n=96	Indeterminate n=26	Malignant n=4
Irregular margins	12 (8.2)	9 (9.4)	1 (3.8)	2 (50)
Microcalcifications	11 (7.5)	7 (7.3)	2 (7.7)	2 (50)
Absence of halo	61 (41.5)	43 (44.8)	14 (53.8)	4 (100)
Hypoechogenicity	43 (29.2)	28 (29.2)	13 (50)	2 (50)
Solid	65 (44.2)	44 (45.8)	20 (76.9)	1 (25)
Solitary	24 (16.3)	18 (18.8)	3 (11.5)	3 (75)
AP/Tr >1	35 (23.8)	25 (26)	8 (30.8)	2 (50)
AP/CC >1	15 (10.2)	11 (11.4)	3 (10.3)	1 (25)

Data are presented as n (%).
AP, anteroposterior; Tr, transverse; CC, craniocaudal.

Statistical analysis

Numeric data were presented as average, standard deviation, median, maximum, and minimum, while categorical data were presented as number and percentage. Correlations between quantitative data with normal distribution were evaluated by Spearman correlation analysis. Categorical data were compared by Fisher exact test. All analyses were performed at the confidence level of 95%. Statistical significance was set at P <0 .05. Statistical data editing and analysis were performed using SPSS 20.0 software (IBM Corp.).

Results

FNAB procedure was performed in a total number of 147 thyroid nodules in 138 patients for cytologic evaluation and the results were classified with reference to the Bethesda System. According to this classification, 21 nodules (14.3%) were nondiagnostic, 96 (65.3%) were benign, 18 (12.2%) were atypic of undetermined significance or follicular lesion of undetermined significance, six (4.1%) were follicular neoplasm or suspicious for a follicular neoplasm, two (1.4%) were suspicious for malignancy and four (2.7%) were malignant. For the purpose of analysis, we combined subgroups of atypia, follicular neoplasm or suspicious for a follicular neoplasm, and suspicious malignancy, which do not meet the necessary criteria for classification into benign or malignant groups, in the "indeterminate" group, also known as the "gray zone" in thyroid cytopathology. Nodule characteristics are presented in Table 1.

Considering the largest diameter among anteroposterior, transverse, and craniocaudal axes diameters, the smallest nodule was 5 mm, the largest nodule was 57 mm, and the mean diameter was 17.6 mm. Multinodular thyroid glands accounted for 81.3% of the benign and 88.5% of the indeterminate nodules, while 75% of the malignant nodules were solitary, with statistically significant difference between the diagnostic groups (P = 0.027).

A diagnostic result could be obtained in 77.8% of subcentimeter nodules and 86.9% of nodules 1 cm or greater in size, with no statistically significant difference between the groups (P = 0.241).

Cystic components were found in 66.7% of nondiagnostic nodules, 54.2% of benign nodules, and 75% of malignant nodules. Indeterminate nodules were solid in 76.9%. Presence of cystic component was significantly different between the diagnostic groups (P = 0.006).

Using the 21G modified Menghini type needle, diagnostic results were not achieved in 21 nodules (14.3%) because of various reasons. Adequate samples for cell block analysis were obtained in a total of 47 nodules (32%), 17 of which contributed to the diagnosis. Samples for cell block were obtained in 38 benign nodules (39.6%), 11 of which had additional contribution to the diagnosis, and in eight indeterminate nodules (30.8%), six of which had additional contribution to the diagnosis. Cell block was obtained in only one malignant nodule, but there was no additional contribution (Table 2). In terms of nodule characteristics, cell block samples were obtained in 36.1% of cystic and 38.5% of solid nodules. Samples for cell block analysis were obtained in 72.3% of nodules with one aspiration, 25.6% of nodules with two aspirations, and 2.1% of nodules with three aspirations.

While the difference between diagnostic cytopathology results and the contribution of the cell block were found to be statistically significant ($P = 0.038$), cell block sample obtainability was not significantly correlated with the number of aspirations or the presence of cystic component in the nodule ($P = 0.888$ and $P = 0.855$, respectively).

We achieved diagnostic cytopathology results in 126 nodules. Diagnosis could be reached with one aspiration in 71.4% of the nodules, two aspirations in 27% of the nodules, and three aspirations in 1.6% of the nodules. Mean aspiration number was found to be 1.4±0.5 in diagnostic aspirations. We could not get adequate sample for five nodules even after three aspirations. One aspiration was sufficient in 78.1% of the benign nodules and 75% of the malignant nodules, while indeterminate nodules required one aspiration in 46.2% and two aspirations in 50%. Number of aspirations was significantly different between the diagnostic cytology results ($P = 0.006$).

One-third of the patients suffered no pain during FNAB with 21G needle. In the rest, the degree of pain stated by the patients was low, medium, and high, in 48.3%, 15.7%, and 2.7%, respectively. In total, 35.8% of patients having only one aspiration and 42.8% of patients having three aspirations reported no pain. There was no statistically significant correlation between the presence of pain and the number of aspirations ($P = 0.857$).

We did not encounter any major complications during or after the intervention. Only one patient (0.7%) had minor hematoma limited to the thyroid gland, which showed no increase in size during the follow-up.

Discussion

Although thyroid nodules are very common, thyroid cancer accounts for 1% of all cancers, and death due to thyroid cancer is seen only in 0.5% of the population (7). Success in the diagnosis and treatment of thyroid nodules can only be achieved with a multidisciplinary approach; collaboration of clinicians, radiologists, and pathologists is crucial. In radiologic examination, US is the first line method accepted for diagnosis of the thyroid gland diseases around the world, as it is noninvasive, easily accessible, feasible, and fast. Today, especially as a result of the development of high-resolution US devices and the use of high-frequency (7–13 MHz) transducers, even very small thyroid lesions of 2–3 mm can easily be detected (4). Detecting these clinically nonpalpable nodules by US also brought up the question of finding which nodules are malignant and require surgery. For this purpose the relationship between malignancy and many suspicious US findings were investigated, but there appears to be no single criterion sufficient to rule out malignancy (8–10). Thus, the current consensus states that US mainly determines which thyroid nodules are suspicious for malignancy and require FNAB, rather than the discriminating benign versus malignant (4).

In this study, we mostly performed FNAB procedure in nodules of 1 cm or greater in size and in subcentimeter nodules with suspicious US findings. However, sometimes at the request of patients or clinicians, nodules without risk factors or sonographic findings suggestive of malignancy were also included in the study. Obtaining cytologic samples in large nodules is easier than in small ones, and diagnostic rates are usually higher in larger nodules (6). However, Degirmenci et al. (11) reported their highest specimen adequacy rates in subcentimeter nodules (76.4%) and lowest rates in nodules greater than 3 cm (56.9%) . These low diagnostic rates were associated with increased vascularity of the nodules and bloody samples, which make cytologic analysis difficult. In addition, other causes like cystic and necrotic areas in large nodules were shown as reasons of inadequate cytology (11). In our study, diagnostic result could be obtained in 77.8% of subcentimeter nodules and 86.9% of nodules 1 cm or greater in size. Rates of samples obtained for cell block analysis were also not statistically significant between subcentimeter nodules and nodules of 1 cm or greater in size (35.7% and 37.5%, respectively).

There are many factors causing inadequate samples and false negative results such as operator experience, size and type of the needle, accessibility of the lesion, US- or palpation-guided procedure, number of aspirations, sampling technique, and cytologic analysis during the procedure (6). In addition, factors like inadequate preparation and fixation, hemorrhage, necrotic material or debris that mask the cellular details affect the rates cytologic diagnosis (12). Inadequate cytologic result rate is increased due to cystic component of the nodule; operator inexperience may also increase this rate up to four times. On the contrary, evaluation of the adequacy of the samples during the process by the cytopathologists leads to a 1.5-fold decrease in the rate of nondiagnostic results (13). In our study, nondiagnostic cytology rate was 14.3%, corresponding to 21 nodules. Reasons for nondiagnostic results were as follows: six nodules were predominantly cystic and were biopsied due to social indications; five nodules were sampled once (one aspiration) because of patients' noncompliance; five nodules did not yield adequate sample even after three aspirations (three of these were subcentimeter nodules and two were located inferoposteriorly on the thyroid gland). Compared with most studies in literature, our nondiagnostic cytology result rates seem to be similar. The rates were higher than our expectations due to reasons mentioned above. Exclusion of these nodules would decrease our nondiagnostic test results, but we do face the same problems in FNAB procedures that are being performed by 27G needles in routine.

With the use of 27G needles and 10 mL syringe, diagnosis is only reached by cytologic sample, while 21G modified Menghini type needle can obtain both cytologic sample and microtissue fragments for cell block analysis leading to histologic diagnosis. Anesthetic injection is not required in FNAB procedures performed with 27G needle. However, 1–2 mL intradermal anesthetic injection is applied before biopsies with 21G needles to reduce the pain felt while pricking through the skin, providing convenience for recurrent aspirations and increasing the diagnostic rate. Most authors recommend two to four aspirations to obtain adequate sample for diagnosis (14, 15). Adequate sampling can be done with three aspirations in most nodules 1–2 cm in size (15).

Table 2. Nodules with cell block analysis and its contribution to diagnosis

Diagnostic groups		Cell block No	Cell block Yes: Contribution to diagnosis (+)	Cell block Yes: Contribution to diagnosis (-)	Total
Benign	Number	58	11	27	96
	Line %	60.4	11.5	28.1	100
	Column %	73.4	64.7	90	76.2
Indeterminate	Number	18	6	2	26
	Line %	69.2	23.1	7.7	100
	Column %	22.8	35.3	6.7	20.6
Malignant	Number	3	0	1	4
	Line %	75	0	25	100
	Column %	3.8	0	3.3	3.2
Total	Number	79	17	30	126
	Line %	62.7	13.5	23.8	100
	Column %	100	100	100	100

Needles 20G–27G in size are generally used for thyroid FNAB (6). Correlation between the size of the needle and specimen cellularity is a subject often discussed in the literature. In two different prospective studies comparing the specimens obtained by 23G versus 27G and 21G versus 25G needles, no significant differences were found (16, 17). Some authors recommend the use of 25G or thinner needles, especially in hypervascular thyroid nodules (18). Adequate cytologic sample rates have been increasing with the use of thinner needles during FNAB due to less hemorrhage; adequate sample rates were reported as 56.6% and 82.5% for 20G and 24G needles, respectively (11).

To our knowledge, there has been only one study with 21G vacuum-assisted modified Menghini type needle used for thyroid nodule FNAB in the literature. In their study, Nasrollah et al. (19) used 21G Menghini needle (10 cm, 0.514 mm) in repeated biopsies of 40 patients with cytology results of previously undetermined significance, and thus avoided surgery in 35% of patients by revealing a benign diagnosis.

Cell block cytology shows the structural details of the thyroid lesions very well and, with the help of immunohistochemical staining, can distinguish benign and malignant thyroid nodules with high diagnostic accuracy (20, 21). Also cell block studies were found to be helpful in the diagnosis of papillary thyroid carcinoma and nodules that are suspicious for malignancy, since they show the configuration and nuclear features better. Hegazy et al. (22) reported that inadequate smear rates in thyroid FNAB were reduced from 15% to 5.8% with the use of 23G or 24G disposable needles. In our study, using 21G vacuum-assisted modified Menghini type needle, adequate samples for cell block analysis were obtained in 47 nodules (32%), 17 of which contributed to the diagnosis. Using a cell block helped us diagnose 11 nodules (11.5%) as benign and six nodules (23.1%) as indeterminate, compared with classical cytopathology. Totally, cell block analysis contributed to diagnosis of 13.5% of all nodules. Particularly, 23.1% of indeterminate nodules could be diagnosed thanks to cell block analysis. Number of nodules with cell block analysis and its contribution to diagnosis are shown in Table 2.

The use of thick needles might be a problem in terms of tolerance in FNAB procedures. Nasrollah et al. (23) reported no significant difference in tolerance of the patients in a comparison of 21G and 23G needles. In their study, 8.2% of the patients reported severe pain with the use of 21G needle. In our study, only 2.7% of the patients stated severe pain, while 33.3% of the patients suffered no pain during the FNAB with 21G needle.

We did not encounter any major complications during the intervention or afterwards. Only one patient (0.7%) had minor hematoma limited to the thyroid gland and it showed no increase in size during the follow up. Nasrollah et al. (23) reported one patient (1.6%) with a minor hematoma with the use of the same needle.

Our study has some limitations. US examination and evaluation of the nodule characteristics have been performed by a single radiologist before the FNAB procedure, therefore we were unable to calculate interobserver variability. As reported in the literature, due to both limited contribution to the diagnosis and considerable extension of procedure time, we ignored Doppler US findings of the nodules. The nodules reported as nondiagnostic and of indeterminate cytology could not be followed for additional data regarding the contribution of the needle.

In conclusion, 21G vacuum-assisted modified Menghini type needle is a safe procedure with very low complication rates, and it is comfortable for both patient and practitioner when used under local anesthesia and with US guidance. Cell block obtainability was the most important advantage of this needle independently from the number of aspirations and the presence of a cystic component. Due to this advantage, the same needle can also be used in many deep organ biopsies other than thyroid such as pancreas and liver, especially in cases where it is difficult to reach the lesion for repetitive biopsies. Need for subcutaneous anesthetic injection, cost, and coordinating biopsy appointments to ensure accompaniment by a pathologist might be some disadvantages compared with disposable 27G needle. However, we believe that with user experience and selection of thyroid nodules for FNAB according to the appropriate indications, nondiagnostic results can be further reduced and the rate of adequate samples for cell block analysis can be increased.

Conflict of interest disclosure

The authors declared no conflicts of interest.

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