

“Wet suction technique (WEST)”: a novel way to enhance the quality of EUS-FNA aspirate. Results of a prospective, single-blind, randomized, controlled trial using a 22-gauge needle for EUS-FNA of solid lesions

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Background: Contemporary EUS-guided FNA techniques involve the use of a needle, with an air column within the lumen, with or without suction. We describe a novel technique with an aim to improve the quality of the aspirate.

Objective: To compare a novel “wet suction” technique (WEST) with the conventional FNA technique (CFNAT) of EUS-guided FNA using a 22-gauge FNA needle.

Design: Prospective, single-blind, and randomized trial.

Setting: Two large tertiary-care hospitals.

Patients: All consecutive adult patients presenting for EUS with possible FNA of solid lesions were offered the chance to participate in the study.

Methods: All lesions were sampled with the same needle by using alternating techniques. Patients were randomized to the WEST versus the CFNAT for the first pass. If the first pass was made with the WEST, the second pass was made with the CFNAT, and subsequent passes were made in an alternating manner by using the same sequence. All FNAs were performed using 22-gauge needles.

Main Outcome Measurements: Specimen adequacy, cellularity, and blood contamination of EUS-guided FNA aspirates graded on a predefined scale.

Results: The WEST yielded significantly higher cellularity in a cell block compared with the CFNAT, with a mean cellularity score of 1.82 ± 0.76 versus 1.45 ± 0.768 ($P < .0003$). The WEST cell block resulted in a significantly better specimen adequacy of 85.5% versus 75.2% ($P < .035$). There was no difference in the amount of blood contamination between the 2 techniques.

Limitations: Lack of cross check and grading by a second cytopathologist.

Conclusion: The novel WEST resulted in significantly better cellularity and specimen adequacy in cell blocks of EUS-guided FNA aspirate of solid lesions than the CFNAT. (Gastrointest Endosc 2015;81:1401-7.)

(footnotes appear on last page of article)

The addition of FNA sampling to EUS has resulted in widespread adoption of EUS as the diagnostic modality



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of choice to obtain a tissue diagnosis in multiple conditions.^{1,2} EUS-guided FNA is now being routinely used to sample various lesions involving the pancreas, liver, gastric wall, adrenal glands, kidney as well as lymph nodes in areas adjacent to the GI tract.

EUS-guided FNA (EUS-FNA) is performed by passing a needle through a working channel located within the echoendoscope. After the needle is passed into the lesion of interest, varying degrees of suction are applied to obtain

an aspirate. Currently, multiple needle types and aspiration techniques are in use without a clear consensus on the optimal aspiration technique.

We describe a novel technique of flushing the needle with 5 mL of saline solution to replace the column of air within the lumen of needle with saline solution before needle aspiration. The technique was developed with an aim to improve the quality of aspirates for cytopathological diagnosis.

PATIENTS AND METHODS

Study design

The aim of the study was to compare the quality of aspirates obtained by using the WEST with those obtained by the CFNAT by using 22-gauge needles for EUS-guided FNA of solid lesions. The study was a prospective, randomized, single-blind, controlled trial performed at 2 large tertiary-care centers.

All consecutive patients 18 years of age and older referred for EUS-FNA of solid lesions to the 2 participating centers, University of Minnesota Medical Center (UMN) (Minneapolis, Minn) and Aurora St. Luke's Medical Center (AMC) (Milwaukee, Wisc), from January 2013 to November 2013 were offered participation in the study. Institutional review board approval was obtained at both participating centers. Informed consent was obtained from all participants. The trial was registered in ClinicalTrials.gov (ClinicalTrials.gov Identifier: NCT01720745; October 25, 2012). Patients with coagulopathy (international normalized ratio >1.5, platelets <50,000) and cystic or solid cystic lesions were excluded.

Various data such as patient demographic characteristics, indication for EUS-FNA, anesthesia used, the number of passes performed, and adverse events (immediate and long term) were recorded. No patient-identifying data were recorded.

METHODS

The study was performed by using a 22-gauge needle (EchoTip Ultra HD; Cook Endoscopy, Winston-Salem, NC) with an identical suction method. For the "wet suction" technique (WEST), after removing the stylet, the needle was flushed with 5 mL of saline solution to replace the column of air with saline solution. A 10-mL suction syringe, loaded to maximal suction, was attached in a "locked" position to the needle after flushing the needle with saline solution (Figs. 1 and 2).

For the conventional FNA technique (CFNAT), the stylet was removed from the needle before performing EUS-FNA. A 10-mL syringe, loaded to maximal suction, was attached in a "locked" position to the needle. Suction was applied after the lesion was punctured.

Procedures were performed by 1 of the 4 experienced endosonographers (each with experience performing >1000 EUS procedures) (R.A., M.A., M.C., N.G.). Patients received moderate conscious sedation or monitored anesthesia care. Procedures were performed by using a linear Olympus echoendoscope (GF UCT 180; Olympus America Inc, Center Valley, Pa) with a Pro Sound processor (Aloka, Wallingford, Conn).

Once the target lesion was identified and intervening blood vessels excluded, the needle was passed into the desired lesion. Suction was applied at maximal strength, and the needle moved back and forth within the lesion 16 to 20 times to obtain an aspirate. In the WEST, drops of saline solution could be seen moving into the suction syringe as the aspirate moved into the needle. The needle was withdrawn, and the aspirate delivered onto a slide by using a stylet. The needles were then flushed with 2 mL of saline solution to ensure removal of all aspirate into the formalin container.

All solid lesions in the study were sampled by using both the WEST and CFNAT in alternating manner with the same needle. If the first pass was made by using the WEST, the next pass was made by using the CFNAT, and subsequent passes were made by alternating technique by using the same sequence (eg, WEST/CFNAT/WEST/CFNAT or CFNAT/WEST/CFNAT/WEST).

At UMN, where an on-site cytopathologist was present, a drop of the expressed aspirate was placed on a slide and 2 smears made. One slide was stained with Diff-Quick stain for immediate interpretation for adequacy, whereas the other slide was fixed in 95% alcohol for Papanicolaou stain. The remainder of the aspirate was sent in 2 formalin bottles (1 for each type of aspiration technique), labeled as A or B, for cell-block analysis. The on-site cytopathologist and technicians were blinded to the aspiration technique.

At AMC, all the aspirates were expressed into separate formalin containers, 1 for each type of aspiration technique labeled A or B and sent for cell-block analysis. No slides were prepared for immediate on-site interpretation at AMC. The number of passes at UMN was determined by the on-site cytopathologist. At AMC, the number of passes was determined by the endosonographer. In most cases, 4 to 6 passes were made per lesion.

Randomization schedule

Enrollment of participants was carried out by the endoscopist performing EUS-FNA. All sampled lesions were randomized to first pass with the WEST versus the CFNAT by using a predetermined, unrestricted randomization schedule generated by SAS software version 9.2 (SAS Institute, Cary, NC).

The randomization schedule was maintained by the coordinator at each site. The assignment labels were kept in sealed opaque envelopes in numerical sequence

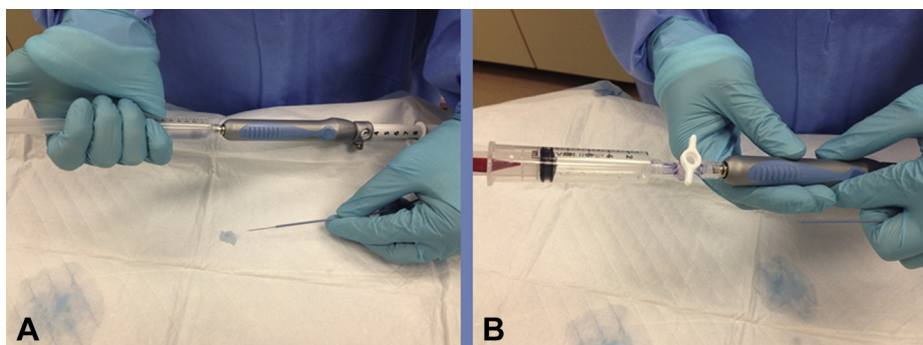


Figure 1. Wet suction technique needle preparation with saline solution (A) and loading suction syringe in the locked position (B).

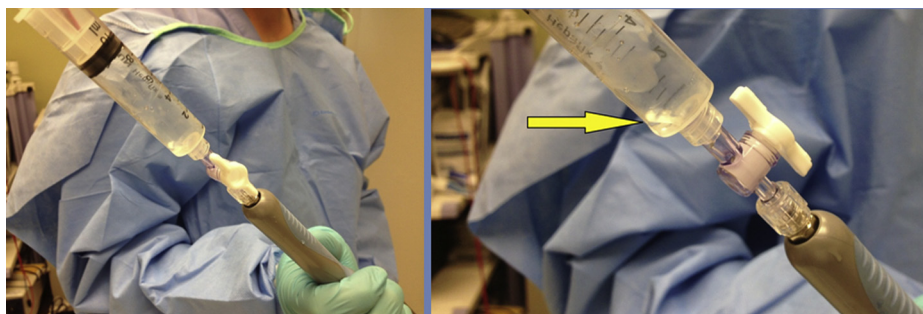


Figure 2. Column of saline solution (arrow) moving into the suction syringe as FNA is performed.

according to the randomization schedules generated by SAS software.

Cytopathological assessment

All study specimens were reviewed and graded by 2 experienced cytopathologists (1 at each site) who had access to clinical information pertaining to the case including age, sex, and site of lesion.

The cell-block specimens were graded on a previously validated scale for cellularity, blood contamination, and adequacy.³ Cellularity was assessed by using a 4-point scale (0 = no cells, 1 = sparsely cellular, 2 = moderately cellular, 3 = highly cellular). Blood contamination was graded on a 3-point scale (0 = free of blood, 1 = contaminated with red blood cells, 2 = blood clots present). Specimen adequacy was graded on a 2-point scale (score 0 = if the cytopathologist was unable to make a diagnosis based on the aspirates and a score of 1 = if adequate tissue was present for the cytopathologist to reach a diagnosis).

Outcome variables

The primary outcome was defined as the adequacy of specimens obtained by EUS-FNA with each aspiration technique. A specimen was defined as adequate if it

had sufficient material for the cytopathologist to reach a cytopathological diagnosis. The secondary outcomes included the degree of cellularity and blood contamination of specimens obtained by the 2 aspiration techniques.

Statistical analysis

Based on our preliminary experience in extracting tissue with the novel technique, we hypothesize that the WEST would yield higher tissue adequacy compared with dry technique. To test this hypothesis, we performed a 1-tailed χ^2 test with $P < .05$ for statistical significance.

A sample size of 117 specimens provided us with a power of 0.8 and an α value of .05 for the comparison of specimen adequacy, mean cellularity, and blood contamination of the specimens with the WEST and CFNAT. All category variables were described in terms of the count and percentage, whereas the continuous variables were described as mean $\pm$ standard deviation. A χ^2 test was used to compare the proportion of the patients with WEST and CFNAT adequacy (0 and 1). Sensitivity, specificity, positive predictive value, and negative predictive value were computed using a 2×2 table for WEST and CFNAT specimen adequacy (yes and no). To compare the mean cellularity and blood contamination between the 2 aspiration

techniques, a 1-tailed χ^2 test was used with $P < .05$ for statistical significance. All statistical analyses were done by using SAS software version 9.2.

RESULTS

A total of 118 patients qualified and consented to participate in the study. Ninety-five of these patients had a solid lesion requiring FNA and hence were included in the final analysis. A total of 117 lesions were sampled, and their cell block was later evaluated by the study cytopathologist. The most commonly sampled lesion was pancreatic followed by lymph nodes. Patient age ranged from 26 to 87 years, with a median age of 61 years (Table 1).

A total of 72 lesions were sampled at UMN with a mean number of passes per lesion of 4.20 ± 1.31 . At AMC, the total number of lesions sampled was 45, with a mean number of passes of 3.22 ± 1.05 . A positive cytological diagnosis of malignancy (confirmed and/or suspicious for malignancy) was achieved in 63 lesions. Atypical cells were seen in 3 patients, and in 5 patients, aspirates were read as nondiagnostic (pancreas, 1; lymph node, 4). Thirty-seven lesions were read as negative for malignancy. Nine other lesions were read as benign, including a small GI stromal tumor.

WEST was used as the first-pass technique when sampling 59 lesions (50%). The total number of passes performed by using the WEST and CFNAT were 221 and 227, respectively.

Adequacy of specimens

In 112 of 117 sampled lesions, cytopathologists had adequate specimens with which to reach a diagnosis. Of the 5 inadequate specimens, 1 was from a peripancreatic lesion and 4 from lymph nodes. The peripancreatic lesion was seen in a patient with a history of pancreaticoduodenectomy. The sampled lesion remained stable in size on serial imaging and was thought to be postsurgical scar tissue. The four lymph nodes read as nondiagnostic had a low suspicion of malignancy.

A WEST cell-block resulted in a significantly better specimen adequacy of 100 of 117 (85.5%) compared with the CFNAT (88/117, 75.2%; $P = .035$) (Table 2).

In 7 lesions, the WEST provided a diagnosis of malignancy, whereas the CFNAT aspirates were either hypocellular or negative for malignancy. In 1 patient, the CFNAT aspirate was diagnostic for malignancy, whereas the WEST aspirate was read as hypocellular.

Cellularity

As described previously, cellularity was graded on a linear scale of 0 to 3. The WEST provided aspirate specimens with a higher mean cellularity score of 1.82 compared with 1.45 with the CFNAT ($P = .0003$).

TABLE 1. Demographic characteristics and lesions sampled

	Total = 117 N (%)
Sex	
Male	66 (56.4)
Female	51 (43.6)
Mean age, y	60.8
Pancreas	63 (54)
Lymph node	35 (30)
Liver	10 (9)
Others	9 (7)

A larger proportion of aspirates with the WEST were read as moderate and high cellularity compared with the CFNAT (WEST: 67.5%, C: 44.4%; $P = .0006$) (Table 2). On the other hand, acellular and poorly cellular specimens were more frequent with the CFNAT (WEST: 32.5%, CFNAT: 45.6%; $P = .0006$) (Table 2).

The WEST provided higher mean cellularity scores even when it was not used as the first-pass technique. The mean cellularity of the WEST with the CFNAT as the first-pass technique was 1.85 versus 1.52 for the CFNAT as aspirate ($P = .02$) (Table 3). When the WEST was used as the first-pass technique, the difference in mean cellularity was more pronounced (WEST: 1.79, CFNAT: 1.38; $P = .0046$) (Table 3).

There was no difference in the amount of blood contamination between the 2 techniques (Table 2). There were no adverse events related to FNA (WEST or CFNAT) in the study group.

DISCUSSION

EUS-FNA has become the modality of choice for obtaining tissue to aid in the diagnosis and management of various intra-abdominal and mediastinal lesions.² However, the technique is far from optimal, with as many as one-fourth of endosonographers reporting sensitivity less than 60% for the diagnosis of solid mass lesions and false-negative rates as high as 19%.^{4,5} Poor cellularity of the aspirates is a common cause of the lack of a diagnosis, resulting in repeated procedures and a delay in reaching a diagnosis, which not only leads to patient anxiety but also delayed treatment or worse a misdiagnosis, which can have serious consequences for patient survival.

In 1930, Martin and Ellis⁶ first presented their results of a tumor diagnosis by needle aspiration by using an 18-gauge needle mounted on a 20-mL syringe. The same technique was adapted for EUS-FNA and has undergone only a few modifications over the past 8 decades. Some of the modifications include changes in needle design (reverse

TABLE 2. Results

	CFNAT	WEST	P value
First pass, no. (%)	60 (51.3)	57 (48.7)	NS
Specimen cellularity score, no. (%)			
0	10 (8.55)	4 (3.42)	.16
1	55 (47.01)	34 (29.06)	.007
2	41 (35.04)	58 (49.57)	.03
3	11 (9.40)	21 (17.95)	.08
Cellularity score, mean $\pm$ SD	1.45 $\pm$ 0.78	1.82 $\pm$ 0.76	.0003
Acellular and poor cellularity (scores of 0 and 1), no. (%)	65 (55.56)	38 (32.48)	.0006
Moderate and high cellularity (scores of 2 and 3), no. (%)	52 (44.44)	79 (67.52)	
Specimen tissue adequacy (yes), no. (%)	88 (75.21)	100 (85.47)	.035
Specimen blood contamination score, no. (%)			
0	40 (34.19)	34 (29.06)	.48
1	59 (50.43)	62 (52.99)	.79
2	18 (15.38)	21 (17.95)	.72

CFNAT, conventional FNA technique; WEST, wet suction technique; NS, not significant; SD, standard deviation.

TABLE 3. Mean cellularity by first-pass FNA technique and specimen status

	CFNAT specimen cellularity		WEST specimen cellularity		P value
	Mean	SD	Mean	SD	
Dry first pass (N = 60)	1.52	0.79	1.85	0.79	.02
Wet first pass (N = 57)	1.38	0.77	1.70	0.72	.0046

CFNAT, Conventional FNA technique; WEST, wet suction technique.

bevel-tip needles) and use of variable amounts of suction, including fine-needle capillary sampling, in which the needle is passed into the target lesion and a specimen is obtained without the use of suction.

We developed the WEST over a period of time with an aim to improve the quality and diagnostic value of the aspirates and reduce the number of passes and procedures to achieve a cytopathological diagnosis. We saw an improvement in the quality of aspirates obtained from an EUS-FNA pass when the needle had been flushed with saline solution to unclog it. As our usual practice did not involve the use of a stylet, we thought that the presence of a saline-solution column might keep the needle from getting clogged while avoiding the inherent inconvenience of a metal stylet. This led to the development of our technique of routinely using a saline solution flush before all passes and eventually replacing the column of air with saline solution.

In this prospective, randomized, controlled, single-blind trial, the WEST was found to improve cellularity and adequacy of the aspirate on cell-block analysis. The trial was designed to remove operator, lesion, and needle bias by

using the same endoscopist sampling a lesion with 1 needle with alternating passes by using the 2 techniques.

Although we do not know the exact mechanisms by which the WEST resulted in improved cellularity and diagnostic yield, there are several possible reasons. First, a column of saline solution may allow for better transmission of applied suction compared with a column of air within the needle. Second, saline solution may coat the inner lining of the needle and thereby change surface properties, leading to easier movement of the aspirate into the needle. Third, as stated previously, the column of saline solution may act as a stylet, thereby potentially reducing the contamination from GI tissue during the needle puncture into a lesion and keeping the needle “unclogged.”

It is possible that the presence of a saline solution column improves the transmission of suction force across the length of the needle, thereby improving the quality of the aspirate. The original FNA techniques were described as using negative pressure applied to the aspiration needle, and it was believed that the role of suction is not to draw cells into the needle lumen, but to hold the target tissue firmly against the cutting edge of the needle as it is moved through the tissue. Use of suction has been shown to increase cellularity of the aspirate, increase sensitivity, and provide cores of tissue. In their study of EUS-FNA involving mediastinal lymph nodes, Bhutani et al⁷ reported improved cellularity with continuous suction. Puri et al⁸ found use of suction to be associated with higher sensitivity and negative predictive in their prospective, randomized trial involving 52 mass lesions. In a study by Lee et al,⁹ the quality of aspirates was better in terms of cellularity when suction was used during EUS-FNA. Similarly, use

of high suction pressures has also led to retrieval of cores of specimen.¹⁰

Recently, there has been a trend of using little or no suction with FNA as it believed that FNA without suction (fine-needle capillary sampling) may improve specimen quality by reducing the amount of blood in aspirated material.¹¹ When FNA with suction was compared with the “slow-pull technique” in which withdrawal of the stylet provides gentle suction, the use of suction resulted in significantly higher scores for cellularity but concurrently increased blood contamination of the specimen, thereby reducing the overall sensitivity with a 25-gauge needle. There was no difference in the quality of aspirates between FNA with suction and the slow-pull technique when a 22-gauge needle was used.¹²

As suggested by the cited studies, the use of suction may improve cellularity and the quality of aspirate, but at the cost of increased bloodiness and contamination. The increased bloodiness and contamination may lead to reduction in diagnostic accuracy, thereby negating any benefits of higher cellularity. However, in our study, we did not find an increase in bloodiness between the 2 techniques, even though the cellularity was much better with the WEST. It is possible that the presence of saline solution eliminates the “empty space” in the needle lumen for the tissue to bleed into, thereby reducing the amount of bloodiness. This is merely a hypothesis without any available scientific evidence.

Another explanation for improved cellularity and increased diagnostic yield of the WEST is potentially a change in the inner surface properties of the needle hollow when coated with normal saline solution. Normal saline solution may reduce the friction between the tissue aspirate and needle wall and allow for smoother movement of the material within the needle. It is our hypothesis that the presence of saline solution in the needle lumen during FNA results in a true “capillary action” effect such that as the tissue aspirate moves up higher within the needle, space is created for more tissue to move into the needle lumen. Conversely, the lack of saline solution within the needle lumen may result in a needle becoming plugged with tissue so that further to-and-fro movement of the needle in the target lesion results in more trauma and blood contamination.

The WEST has several potential benefits. The technique involves minimal modifications to the conventional aspiration techniques and can therefore be performed easily and without any significant additional costs. In addition, the act of flushing saline solution through the needle after each pass does not add any significant amount of time and may actually have the benefit of ensuring that the entire aspirate is expressed into the formalin jar rather than tissue being left behind in the needle lumen. The WEST also does not involve the use of a stylet during tissue acquisition, which many find cumbersome and time-consuming.

In our study, no adverse events were associated with the WEST. Attaching the suction syringe in a locked position ensured that the column of saline solution remained within the needle before puncture of the target lesion. Once the lesion was punctured, use of suction and a forward jabbing motion of the needle ensured aspiration of saline solution and target tissue rather than the saline solution being injected into the lesion.

Our study has limitations that include the lack of a cross-check of cytopathological grading by a second cytopathologist. In addition, on-site cytological evaluation was only performed at 1 institution (UMN). To control for this, only cytopathological assessment from cell-block specimens was used for the purposes of the study. This is the first study involving a new technique and even though the preliminary results are very promising, further multicenter studies are warranted before a widespread change in EUS-FNA practice is advocated. Further areas of study include the performance characteristics of the WEST by using different needle sizes and the effect of the WEST on the diagnostic yield of both on-site cytology and cell-block specimens.

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Abbreviations: AMC, Aurora St. Luke's Medical Center; CFNAT, conventional FNA technique; EUS-FNA, EUS-guided FNA; SD, standard deviation; UMN, University of Minnesota Medical Center; WEST, wet suction FNA technique.

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