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# Comparison of specimen adequacy and diagnostic accuracy of a 25-gauge and 22-gauge needle in endobronchial ultrasound-guided transbronchial needle aspiration

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**Background:** Endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) is the preferred diagnostic modality for sampling mediastinal and hilar lymph nodes (LNs). The conventional needle used for sampling is either a 21-gauge (21G) or 22-gauge (22G). A 25-gauge (25G) needle has recently been introduced with little known regarding its efficacy.

**Methods:** A retrospective study was conducted on patients referred for EBUS-TBNA who had LNs sampled using a 25G or 22G needle. A propensity score matching analysis was performed. After matching the groups, each LN was assessed for adequacy and final diagnosis. Non-diagnostic and benign lymphoid specimens were compared with repeat biopsy findings or long-term clinical and radiological follow-up.

**Results:** A total of 158 LNs were included. An adequate sample was obtained in 92.4% (73/79) in the 25G group and 92.4% (73/79) in the 22G group (P=1). The 25G group diagnosed benign lymphoid tissue in 82.3% (65/79), granuloma in 7.6% (6/79) and malignancy in 2.5% (2/79). Six lymph nodes in the 25G group were non-diagnostic (7.6%). The 22G group diagnosed benign lymphoid tissue in 83.5% (66/79), granuloma in 3.8% (3/79) and malignancy in 5.1% (4/79). Six lymph nodes in the 22G group were non-diagnostic (7.6%). The sensitivity, specificity, negative predictive value (NPV) and diagnostic accuracy in the 25G group was 88.9% (95% CI, 51.8–99.7%), 100% (95% CI, 92.1–100%), 97.8% (95% CI, 87.6–99.7%) and 98.2% (95% CI, 90.1–100%), respectively. The sensitivity, specificity, NPV and diagnostic accuracy in the 22G group was 77.8% (95% CI, 40–97.2%), 100% (95% CI, 86.8–100%), 92.9% (95% CI, 79.3–97.8%) and 94.3% (95% CI, 80.8–99.3%), respectively. The 25G and 22G group were comparable in diagnostic accuracy (P=0.7).

**Conclusions:** The 25G and 22G needle achieve comparable specimen adequacy and diagnostic accuracy in EBUS-TBNA.

**Keywords:** Bronchoscopy; lymph node; endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA)

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## Introduction

Endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) is a minimally invasive diagnostic procedure used in the sampling of mediastinal and hilar lymph nodes (1,2). EBUS-TBNA is primarily used in diagnosing and staging lung cancer, but additional applications exist, including evaluation of unexplained mediastinal lymphadenopathy, suspected granulomatous diseases (i.e., sarcoidosis) and lymphoproliferative disorders (2-5). The most recent guidelines from the American College of Chest Physicians (ACCP) and European Society of Thoracic Surgeons (ESTS) recommend EBUS-TBNA as the first-line test for mediastinal staging in non-small cell lung cancer (NSCLC) (1,6).

The literature supports using either a 21-gauge (21G) or 22-gauge (22G) needle in EBUS-TBNA (2). More recently, a 25-gauge (25G) needle has been made available; however, the data to support its use is lacking. The purported advantages of the 25G design include better penetration, greater resistance to deformity and a reduced frequency of specimen contamination with blood (7-10). Studies comparing the 25G and 22G needle in endoscopic ultrasound-guided fine needle aspiration (EUS-FNA) have shown superior diagnostic accuracy of the 25G needle (11).

The aim of this study was to compare specimen adequacy and diagnostic accuracy of the 25G and 22G needle in EBUS-TBNA.

## Methods

We retrospectively collected data from patients referred to our institution for EBUS-TBNA between May 2017 and May 2018. This study was approved by the University Hospitals Cleveland Medical Center Institutional Review Board. We included patients who underwent sampling of mediastinal and hilar lymph nodes using either a 25G or 22G needle during EBUS-TBNA. Exclusion criteria were patients age less than 18 years and patients who had more than one needle gauge used during the procedure.

All procedures were performed using Olympus EBUS bronchoscopes and rapid onsite evaluation (ROSE). Either the 25G Boston Scientific (Boston Scientific, USA) or 22G Olympus ViziShot (Olympus America, USA) EBUS-TBNA needle was used. The needle gauge was selected at the discretion of the bronchoscopist. Each lymph node was assessed for adequacy and final diagnosis based on the cytologist report. Specimens were deemed adequate if lymphocytes or atypical cells were present, or a preliminary diagnosis was made. Specimens were considered diagnostic if malignancy or granuloma was identified (12).

### *Follow-up of non-diagnostic & benign lymphoid tissue specimens*

If a specimen was categorized as benign or non-diagnostic, the case was then reviewed for any follow-up diagnostic studies performed. Patients were followed for a minimum of 6 months from the time of initial sampling. According to methods previously described (13,14), applicable follow-up studies include repeat chest computed tomography (CT) or positron emission tomography (PET) scan, surgical sampling (i.e., mediastinoscopy or lymph node dissection), and/or repeat EBUS-TBNA. Patients who received chemotherapy and/or radiation after initial sampling, those who were lost to follow-up, and those who died during the follow-up period were excluded.

If repeat lymph node biopsy did not provide an alternative diagnosis and/or follow-up imaging was stable, the initial specimen was considered a true negative. If the lymph node enlarged on CT, demonstrated increased fluorodeoxyglucose (FDG) avidity on PET, and/or repeat biopsy identified an alternative diagnosis (i.e., malignancy or granuloma), then the initial specimen was considered a false negative.

### *Statistical analysis*

Based on previous studies (7,9), we estimated the difference in diagnostic accuracy between the two groups after matching to be close to 20%. To have 80% power to detect this difference with a statistical significance level of 0.05, we calculated that the number of lymph nodes in each group needed is 80 lymph nodes.

A propensity score matching analysis was performed using "Multivariate and Propensity Score Matching Software with Automated Balance Optimization: The Matching Package for R" with 1:1 ratio, a caliper of 0.2 and the nearest neighbor method (15). Seventy-nine lymph nodes in the 25G group were matched to seventy-nine lymph nodes in the 22G group. The two groups were matched according to age, gender, smoking status, history of COPD, indication for the procedure, lymph node location, lymph node size, number of passes and bronchoscopist. A chi-square test was used to compare sensitivity, specificity, positive predictive value (PPV), negative predictive value

(NPV) and diagnostic accuracy between the two groups. All data were reported with the corresponding 95% confidence intervals (CI).

## Results

Between May 2017 and May 2018, 112 patients underwent EBUS-TBNA using either a 25G or 22G needle. A total of 242 and 81 lymph nodes were sampled with the 22G and 25G needle, respectively. Baseline characteristics before and after matching are shown in *Table 1*. Prior to matching, the two groups were significantly different regarding their smoking status, history of COPD, indication for the procedure, lymph node size and number of passes. After matching, the two groups achieved comparable baseline characteristics based on P values and standardized mean differences. A plot of absolute standardized difference is shown in *Figure 1*.

Post-matching outcomes analysis using McNemar's test is shown in *Table 2*. An adequate sample was obtained in 73 of 79 lymph nodes (92.4%) in the 25G group and 73 of 79 lymph nodes (92.4%) in the 22G group (P=1). The 25G group diagnosed benign lymphoid tissue in 82.3% (65/79), granuloma in 7.6% (6/79) and malignancy in 2.5% (2/79; two small cell carcinoma). Six lymph nodes in the 25G group were non-diagnostic (7.6%). The 22G group diagnosed benign lymphoid tissue in 83.5% (66/79), granuloma in 3.8% (3/79) and malignancy in 5.1% (4/79; one squamous cell carcinoma and three adenocarcinoma). Six lymph nodes in the 22G group were non-diagnostic (7.6%).

A total of 71 lymph nodes in the 25G group and 72 lymph nodes in the 22G group were categorized as benign or non-diagnostic. Among them, 46 lymph nodes in the 25G group (64.8%) and 28 lymph nodes in the 22G group (38.9%) were eligible for review of any follow-up diagnostic studies performed. Repeat imaging with CT or PET was obtained in 37 lymph nodes (80.4%) in the 25G group and 13 lymph nodes (46.4%) in the 22G group. Surgery with lymph node biopsy was obtained in 8 lymph nodes (17.4%) in the 25G group and 13 lymph nodes (46.4%) in the 22G group.

### *Diagnostic performance of the 25G and 22G needle*

Of the 46 lymph nodes in the 25G group, a total of 45 nodes met criteria for a true negative. One lymph node grew on repeat CT, and was classified as a false negative. Of the 28 lymph nodes in the 22G group, a total of 26 nodes met criteria for a true negative. Two lymph nodes grew on repeat CT, and were classified as false negatives.

The sensitivity, specificity, PPV, NPV and diagnostic accuracy in the 25G group was 88.9% (95% CI, 51.8–99.7%), 100% (95% CI, 92.1–100%), 100%, 97.8% (95% CI, 87.6–99.7%) and 98.2% (95% CI, 90.1–100%), respectively. The sensitivity, specificity, PPV, NPV and diagnostic accuracy in the 22G group was 77.8% (95% CI, 40–97.2%), 100% (95% CI, 86.8–100%), 100%, 92.9% (95% CI, 79.3–97.8%) and 94.3% (95% CI, 80.8–99.3%), respectively.

There was no statistically significant difference in sensitivity, specificity, PPV, NPV and diagnostic accuracy between the two groups with P values of 1, 1, 1, 0.66 and 0.7, respectively.

## Discussion

Through retrospective chart review, our study found no difference in specimen adequacy or diagnostic accuracy of the 25G and 22G needle in EBUS-TBNA. We consider this work to be novel as it addresses a gap in the literature pertaining to the utility of the 25G needle in mediastinal and hilar lymph node sampling. Studies exploring the efficacy of the 25G needle are readily found in the EUS-FNA literature. A meta-analysis by Madhoun *et al.* found the 25G needle achieved a higher diagnostic accuracy compared to the 22G needle in EUS-FNA of solid pancreatic lesions (11). While EBUS-TBNA and EUS-FNA are targeting different sites, the technology employed is similar. Notably, the two can be combined for sampling of mediastinal lymph nodes in NSCLC to offer a more complete staging procedure (16).

### *Potential advantages & disadvantages of the 25G needle*

The high diagnostic accuracy of EBUS-TBNA is dependent upon successful specimen acquisition and interpretation. The 25G needle is unique in its design, specifically the needle is constructed with a cobalt chromium, whereas most EBUS-TBNA needles (including the 22G) are manufactured with a stainless-steel alloy or nitinol. The difference in needle composition may influence its efficiency, including penetrability, resistance to deformity and durability (10).

Studies comparing different needle sizes in EUS-FNA suggest the advantage of the 25G needle lies in its ability to

**Table 1** Baseline patient characteristics before and after propensity matching

| Variable | Before propensity matching | | | After propensity matching | | |
|---|---|---|---|---|---|---|
| | 22G | 25G | SMD | 22G | 25G | SMD |
| n | 242 | 81 | | 79 | 79 | |
| Age [mean (SD)] | 65.03 (10.07) | 63.74 (7.74) | 0.144 | 63.46 (10.29) | 63.80 (7.79) | 0.037 |
| Gender = male (%) | 145 (59.9) | 51 (63.0) | 0.063 | 50 (63.3) | 51 (64.6) | 0.026 |
| Smoking status (%) | | | 0.497 | | | 0.028 |
| Current | 66 (27.3) | 25 (30.9) | | 26 (32.9) | 25 (31.6) | |
| Former | 120 (49.6) | 51 (63.0) | | 48 (60.8) | 49 (62.0) | |
| Never | 56 (23.1) | 5 (6.2) | | 5 (6.3) | 5 (6.3) | |
| COPD = yes (%) | 94 (38.8) | 53 (65.4) | 0.552 | 50 (63.3) | 51 (64.6) | 0.026 |
| Indication (%) | | | 0.577 | | | 0.114 |
| Known lung cancer | 20 (8.3) | 18 (22.2) | | 13 (16.5) | 16 (20.3) | |
| Mediastinal adenopathy | 73 (30.2) | 9 (11.1) | | 8 (10.1) | 9 (11.4) | |
| Suspected lung cancer | 149 (61.6) | 54 (66.7) | | 58 (73.4) | 54 (68.4) | |
| Location (%) | | | 0.397 | | | 0.194 |
| 10L | 4 (1.7) | 0 (0.0) | | 0 (0.0) | 0 (0.0) | |
| 10R | 3 (1.2) | 1 (1.2) | | 2 (2.5) | 1 (1.3) | |
| 11L | 37 (15.3) | 11 (13.6) | | 12 (15.2) | 11 (13.9) | |
| 11R | 53 (21.9) | 24 (29.6) | | 23 (29.1) | 24 (30.4) | |
| 12L | 5 (2.1) | 0 (0.0) | | 0 (0.0) | 0 (0.0) | |
| 2L | 5 (2.1) | 1 (1.2) | | 0 (0.0) | 1 (1.3) | |
| 2R | 3 (1.2) | 3 (3.7) | | 1 (1.3) | 1 (1.3) | |
| 4L | 27 (11.2) | 11 (13.6) | | 12 (15.2) | 11 (13.9) | |
| 4R | 38 (15.7) | 13 (16.0) | | 13 (16.5) | 13 (16.5) | |
| 7 | 67 (27.7) | 17 (21.0) | | 16 (20.3) | 17 (21.5) | |
| Size, mm [mean (SD)] | 9.66 (6.04) | 8.04 (2.30) | 0.355 | 7.84 (3.11) | 8.09 (2.30) | 0.09 |
| Needle passes [mean (SD)] | 4.23 (1.53) | 3.47 (0.79) | 0.627 | 3.52 (0.88) | 3.47 (0.77) | 0.062 |
| Bronchoscopist (%) | | | 0.337 | | | <0.001 |
| A | 229 (94.6) | 81 (100.0) | | 79 (100.0) | 79 (100.0) | |
| B | 6 (2.5) | 0 (0.0) | | 0 (0.0) | 0 (0.0) | |
| C | 0 (0.0) | 0 (0.0) | | 0 (0.0) | 0 (0.0) | |
| D | 7 (2.9) | 0 (0.0) | | 0 (0.0) | 0 (0.0) | |

N, number of lymph nodes; SMD, standardized mean difference; SD, standard deviation; mm, millimeters.

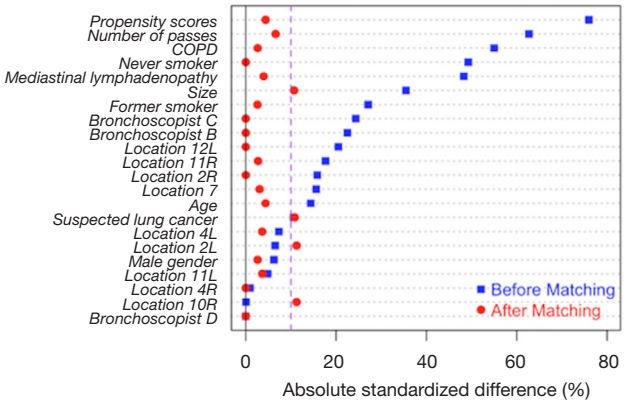


**Figure 1** Absolute standardized difference plot.

**Table 2** Post-matching outcomes analysis

| Variable | 22G | 25G | P value |
|---|---|---|---|
| N | 79 | 79 | |
| Adequacy = yes (%) | 73 (92.4) | 73 (92.4) | 1 |
| Diagnosis | | | |
| Benign lymphoid tissue (%) | 66 (83.5) | 65 (82.3) | 0.83 |
| Malignancy (%) | 4 (5.1) | 2 (2.5) | 0.41 |
| Granuloma (%) | 3 (3.8) | 6 (7.6) | 0.32 |
| Non-diagnostic (%) | 6 (7.6) | 6 (7.6) | 1 |

N, number of lymph nodes.

penetrate firmer lesions (7,8). Although our study excluded patients who had more than one needle used during the procedure, we found success substituting for a smaller needle in instances where the lymph node was difficult to access. This issue of nodal penetrability is often encountered in patients undergoing mediastinal restaging, likely related to fibrosis secondary to prior chemotherapy or radiation (17). The sharpness of the 25G needle also facilitates the to-and-fro movement within the lymph node. This latter point is consequential given that up to 25% of metastases arise in the marginal areas of the node (18).

Another distinct feature of the 25G needle is that fewer specimens are contaminated with blood (9). This is not unusual as prior data have shown larger needles generate bloodier samples (19,20). The presence of blood may obscure diagnostic material, rendering the specimen uninterpretable. This has important implications including failure to ascertain an adequate specimen and potentially increasing the risk of complications through trauma and bleeding (21).

A potential disadvantage of a smaller size needle is the specimen volume is likely to be reduced. Lower quantity specimens are cited as a reason for difficulty in diagnosing lymphoma, where subtyping has important diagnostic and therapeutic implications (4,5). In cases where a diagnosis of lymphoma is suspected or a patient has a history of lymphoma with unexplained mediastinal lymphadenopathy, we tend to favor a larger size needle such as the 21G or 19G.

### *Additional consideration*

After establishing a diagnosis of malignancy, the sample is often sent for additional analysis, including molecular testing (22). EBUS-TBNA can procure ample tissue for such testing; however, operators may be wary of a smaller needle yielding an insufficient sample (23,24). Stoy *et al.* assessed the success rate of next generation sequencing (NGS) testing from cytology smear specimens using either a 25G or 22G needle. The authors found no significant difference between needles with respect to cytologic assessment of adequacy for small or large panel gene testing. Moreover, the number of needle passes did not differ between the groups (25).

### *Limitations*

There are several limitations to this study. First, the retrospective design has its inherent disadvantages, and while we tried to correct for potential confounders by propensity matching, residual unmeasured confounders may have been missed. Second, most lymph nodes were followed with repeat imaging alone, and did not undergo surgical sampling for histologic confirmation. However, in most cases, patients were followed for more than 6 months making the potential for a missed diagnosis (i.e., malignancy) highly unlikely. Third, the 25G needle was used in a single center by an operator trained in interventional pulmonology, which may limit the generalizability of our results.

Finally, despite a large proportion of our referral base having a known or suspected diagnosis of lung cancer, most lymph nodes were found benign. This discrepancy may be explained by several factors. For instance, the mean lymph node size in both groups was less than 1 cm, and while smaller lymph nodes can harbor metastases, the likelihood of malignancy is significantly lowered (26,27). Alternatively, a patient with suspected lung cancer may

undergo a combined procedure with mediastinal staging followed by sampling of the parenchymal lesion. In this case, the mediastinal and hilar nodes are negative, but the lesion may be positive for cancer. Another consideration unique to our geographic region is the high prevalence of fungal infection. Prior studies have shown that in areas of high endemic granulomatous disease, the specificity and NPV of PET/CT is significantly reduced. This is important given that most patients are referred because of suspicious or abnormal findings on initial imaging (28,29).

## Conclusions

The 25G needle and 22G needle achieve comparable specimen adequacy and diagnostic accuracy in EBUS-TBNA. Additional factors such as cost, operator experience and suspected diagnosis should be considered prior to needle selection.

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None.

## Footnote

*Conflicts of Interest*: B Young is a consultant for Pinnacle Biologics, Auris Surgical Robotics and ProVation. The other authors have no conflicts of interest to declare.

*Ethical Statement*: This study was approved by the University Hospitals Cleveland Medical Center Institutional Review Board (No. STUDY20180315).

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