

# Utility and safety of cobalt chromium needles for endobronchial ultrasound-guided transbronchial needle aspiration: a retrospective single-center study

**Keigo Uchimura**

University of Occupational and Environmental Health Japan <https://orcid.org/0000-0001-6379-9583>

**Kei Yamasaki**

University of Occupational and Environmental Health, Japan

**Sachika Hara**

University of Occupational and Environmental Health, Japan

**Takashi Tachiwada**

University of Occupational and Environmental Health, Japan

**Toshinori Kawanami**

University of Occupational and Environmental Health, Japan

**Akira Kisohara**

Kasukabe Medical Center

**Kazuhiro Yatera** (✉ [yatera@med.uoeh-u.ac.jp](mailto:yatera@med.uoeh-u.ac.jp))

<https://orcid.org/0000-0002-2955-4432>

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## Research article

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# Abstract

**Background:** Endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) is a standard method for obtaining specimens of mediastinal and hilar lesions, and several types of needle of various sizes and materials are available. This study aimed to compare the utility and safety of two needles, cobalt chromium (CC) and stainless steel (SS), for EBUS-TBNA. **Methods:** This retrospective study included data of patients who underwent EBUS-TBNA with a 22-gauge needle made from either SS (38 patients, 121 punctures) or CC (39 patients, 145 punctures), and procedure time, histological data, complication rates were compared. **Results:** There were no significant differences between the groups in the baseline characteristics of the patients or lesions or in the complication rates. Although diagnostic yields in each patient who underwent EBUS-TBNA with the two needle types were similar, significantly shorter procedure time (22 min vs. 26 min,  $p = 0.007$ ), diagnostic histologic sampling yield in each sample (71.0% vs. 58.7%,  $p = 0.039$ ), fewer samples with cartilage alone (1.4% vs. 6.6%,  $p = 0.047$ ) and fewer samples containing cartilage (7.6% vs. 16.5%,  $p = 0.034$ ) were seen in the CC group compared with that in SS needle group. **Conclusion:** Compared with SS needles, CC needle for EBUS-TBNA showed significant shorter procedure time and higher ratio of getting diagnostic histological specimens in each sample. This might be because of better ability of CC needle to puncture through the trachea and bronchial cartilage to get appropriate lymph node sampling.

## Background

Endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) has become a standard method for obtaining specimens from mediastinal and hilar lesions in both malignant and benign diseases [1-3]. Several international guidelines have recommended that EBUS-TBNA is the best first test for diagnosing and staging of lymph nodes, especially in lung cancer [4-7]. Recent advances in systemic chemotherapy have demanded larger amount of pathological samples not only for diagnosis but also for molecular testing of gene mutations, immunohistochemistry, biomarkers such as programmed death ligand 1 and applying next generation sequencing to search for novel target genes [8,9]; therefore, adequate tissue sampling in lung cancer has become more important.

High sensitivity and specificity of EBUS-TBNA for lymph node staging in non-small cell lung cancer have been shown [10,11]; however, relatively low diagnostic yield (50%–60%) of stainless steel (SS) needles for obtaining histological specimens per puncture has also been reported [12,13]. Several different types of puncture needles of EBUS-TBNA have recently become available with various sizes (19-, 21-, 22- and 25-gauges), materials [SS, nitinol and cobalt chromium (CC)] and needle tip structures (with or without a reverse bevel). Despite of many comparative studies, the optimal needle for each patient remains unclear [7,14].

CC is 24% harder than SS [15], and the needle tips made of CC are sharper and thinner than those of SS; therefore, CC would be expected to facilitate puncturing of the trachea, bronchial wall and target lesion, thereby improving tissue sampling yield. No studies comparing the diagnostic yields of histological

specimens and safety of these two types of needles have been reported. The aim of this study was to compare the diagnostic yield of histological specimens obtained with 22-gauge CC needle and SS needle and to evaluate their safety profiles.

## Methods

### Patients

This study retrospectively analyzed medical data of consecutive patients with enlarged mediastinal and/or hilar lymphadenopathy and tumors reachable by EBUS-TBNA at Kasukabe Medical Center between July 2016 and December 2017. This study was approved by the institution review board (IRB no: 2017-013), and all participants provided written informed consent.

Lymphadenopathy was defined as an enlargement (>5 mm in short axis diameter) on chest computed tomography (CT) or increased [18F]-fluorodeoxyglucose uptake on positron emission tomography-CT (maximum standardized uptake value >2.5). Prior to EBUS-TBNA, each patient underwent a 1-mm slice chest CT scan, and EBUS-TBNA was performed using 22-gauge SS needles (Vizishot<sup>®</sup> NA-201SX-4022, Olympus, Tokyo, Japan, Fig. 1A and C) used on Mondays and Thursdays (the SS group), and 22-gauge CC needles (Expect<sup>™</sup> Pulmonary E00558220, Boston Scientific Corporation, Natick, MA, USA, Fig. 1B and D) used on Tuesdays, Wednesdays and Fridays (the CC group). Patient clinical characteristics, target lesions, procedure times, complications, diagnostic yield per lesion (including histology and cytology) and successful achievement of diagnostic histological specimens per puncture were compared between these two groups. Diagnostic yields of histological findings of the specimens in these two groups were also compared.

### EBUS-TBNA procedure

#### Needles

A SS needle tip, available as 21- or 22-gauge (Vizishot<sup>®</sup>, Fig. 1A and C) and a CC needle tip, available as 25- or 22-gauge (Expect<sup>™</sup> Pulmonary, Fig. 1B and D) were used.

#### Procedure

EBUS-TBNA were performed using a convex probe ultrasound bronchoscope (CP-EBUS BF-UC260FW; Olympus), and only one needle type (SS or CC) was used for each patient. All the bronchoscopic procedures were performed by bronchoscopists with more than 5 years of bronchoscopic experience,

including extensive experience of EBUS-TBNA, similar to the previous reports [4,7]. Under local anesthesia with midazolam and opioids during the procedure, bronchoscope was orally inserted without intratracheal intubation, and pharynx was initially locally anaesthetized by spraying 4% lidocaine (5 ml), followed by intermittent application of additional 2% lidocaine to the vocal cords, trachea and bronchi via the bronchoscope.

A convex probe transducer of bronchoscope can scan target lesions parallel to the direction of the bronchoscope insertion, and the ultrasound images were evaluated using a dedicated ultrasound processor (EU-ME2 PREMIER, Olympus) in B-mode, with the vascular pattern assessed using power Doppler ultrasound. An internal stylet was used and slightly pulled out to facilitate the punctures. Under real-time EBUS guidance, the target lesion was punctured by the needle through the tracheobronchial wall; the stylet was then deeply pushed into the needle and removed to prevent contamination of the airway cells, bronchial walls and tracheobronchial cartilage [16]. The needle was moved back and forth about 20 to 30 times within the target lesion while applying a negative pressure with a disposable 20-ml syringe. After sampling the tissue, the suction was released and the needle was removed from the bronchoscope. The time from insertion of the bronchoscope into the vocal cords to removal was recorded as the procedure time. The procedure involved three punctures or the collection of two core tissue samples per lesion. After each puncture, the stylet was inserted into the needle and the collected specimen was pushed onto a glass slide and fixed with 10% neutral buffered formalin for histopathological evaluation. The remaining needle aspirate was then blown onto the glass slide and smeared for cytological evaluation. The needle was rinsed with saline and the rinsed fluid was submitted for bacteriological examination. The final diagnosis for each patient was established from the pathological evidence obtained by EBUS-TBNA, surgery, microbiological analysis or clinical follow-up for at least 6 months. Rapid on-site cytology evaluations were not available for all patients. EBUS-TBNA-related complications defined as conditions that required hospital admission, including pneumothorax, hemorrhage, infection and air embolism were documented.

## Pathological evaluation

Pathology was evaluated by independent cytologist and pathologist who were blinded to the needle type. Using a previously reported histological classification [12,13], the histological specimens obtained from the target lesions were categorized into three groups:  $\alpha$ , diagnostic (Fig. 2A);  $\beta$ , non-diagnostic (e.g. blood clot (Fig. 2B) or cartilage (Fig. 2C));  $\gamma$ , no specimens (Fig. 2D). The numbers of specimens classified as  $\alpha$ ,  $\beta$  and  $\gamma$  were used to calculate the diagnostic yield of histological specimens using the formula ( $\alpha / [\alpha + \beta + \gamma]$ ). Blood contamination and cartilage in the specimens were investigated in the present study; the numbers of specimens that contained some cartilage and the numbers of specimens that only contained blood clot or cartilage were compared between the two groups.

## Statistical analysis

Descriptive statistics are presented as frequency with percentage or median (range). Clinical characteristics, procedure time, and numbers of complications were recorded per patient, and the diagnostic yield was calculated per lesion. Differences between the two groups were examined with Fisher's exact test or the Mann–Whitney *U* test, based on a two-sided hypothesis. A *P*-value <0.05 was considered to be statistically significant. The statistical analyses were performed with EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan), which is a graphical user interface for R, version 2.13.0 (The R Foundation for Statistical Computing, Vienna, Austria), and a modified version of R commander (version 1.8-4).

## Results

During the study period, 77 patients underwent EBUS-TBNA for 88 lesions (266 punctures), 38 patients (41 lesions, 121 punctures) in the SS group and 39 patients (47 lesions, 145 punctures) in the CC group. Table 1 summarizes the baseline characteristics of the patients and lesions, and the final diagnoses of the target lesions are listed in Table 2; these included both benign and malignant diseases. No significant differences were observed in clinical characteristics or lesion size and location for two groups. The median procedure time for the CC group was significantly shorter than that for the SS group (22 min vs. 26 min, *P* = 0.007). The diagnostic yields for the SS and CC groups were 75.6% (31/41 lesions) and 85.1% (41/47 lesions), respectively (*P* = 0.29). Comparing the malignancies alone, the diagnostic yields for the SS and CC groups were 87.9% (29/33 lesions) and 92.3% (36/39 lesions), respectively (*P* = 0.69). For lesions <1 cm in short axis size, the diagnostic yields for SS and CC were 100% (4/4 lesions) and 66.6% (2/3 lesions), respectively (*P* = 0.43). For lesions ≥1 cm in short axis size, the diagnostic yields for the SS and CC groups were 86.2% (25/29 lesions) and 94.4% (34/36 lesions), respectively (*P* = 0.39). Only one complication was recorded: one patient in the SS group developed bacterial pneumonitis, which rapidly improved after antimicrobial therapy. There was no significant difference in the incidence of complications between the groups (*P* = 1.0).

Table 3 summarizes the classification of the histological specimens. The diagnostic yield of histological specimens was significantly lower for the SS group than that for the CC group (58.7% vs. 71.0%, respectively, *P* = 0.039).

Histological evaluations of the specimens are summarized in Table 4. The number of the specimens with blood clot only in both groups was insignificant (*P* = 0.81). Compared with the SS group, the CC group had significantly fewer specimens containing some cartilage (16.5% vs. 7.6%, *P* = 0.034) and significantly fewer specimens containing only cartilage (6.6% vs. 1.4%, *P* = 0.047).

## Discussion

This study was the first to evaluate the differences between the SS and CC 22-gauge EBUS-TBNA needles in terms of their diagnostic quality of tissue sampling. The results showed that CC needles demonstrated significantly shorter procedure time and higher diagnostic yields of histological specimens compared with that of SS needles with similar safety profiles. These results suggest that CC needles may be more useful for obtaining adequate diagnostic specimens that lead to accurate diagnoses of hilar and mediastinal lesions.

High diagnostic accuracy of EBUS-TBNA with a cumulative sensitivity of 88%–93% and a cumulative specificity of 100% for lymph node staging in non-small cell lung cancer has been demonstrated in two meta-analyses [10,11]. The diagnostic yields for both needle types in the present study were lower than those in the analysis because benign diseases were included in the analysis. In fact, for malignancies, the diagnostic yields in both groups (SS, 87.9% and CC, 92.3%) were similar to those reported in the previous reports (88%–93%) [10,11]. Similarly, diagnostic yield per puncture of histological specimens obtained using the SS needle in this study (58.7%) was consistent with that reported in previous reports (57%–61.3%) [12,13]. Recent studies have shown that the specimens obtained by EBUS-TBNA are tolerable for genetic analysis, such as next generation sequencing, and immunohistochemical analysis for programmed death ligand 1 [17-20]. Obtaining proper samples with higher diagnostic yield adequate for these additive critical testing for diagnosis and treatment would be considerably beneficial, therefore, improved sampling by modifying EBUS-TBNA needles maybe clinically helpful.

Although the diagnostic yields were similar for both needle types, significantly higher diagnostic yields of histological specimens per puncture and significantly shorter median procedure time were observed in the CC group compared with that for the SS group. Therefore, it is speculated that these results can be attributed to the two particularly important advantages of CC needles for EBUS-TBNA: the sharpness and thinness of the needle tip. CC needles have sharper tips than those of SS needles (Fig. 1C and D), allowing it to puncture the target lesions easily and smoothly through the bronchial wall and cartilage. Similar to CC needle, a retrospective study reported that nitinol needles also had sharp tips that shortened procedure time and improved tissue sampling compared with SS needle, but detailed histological findings of the obtained specimens were not evaluated [12].

Obtaining only cartilage by EBUS-TBNA is frequently experienced, and the present study showed that the tissues obtained with CC needles contained significantly less percentage of samples with only cartilage compared to that of SS needles. Stylets are usually used to reduce contamination of the airway cells, bronchial walls and tracheobronchial cartilage when sampling tissue within the target lesions. A randomized clinical trial reported that using stylets with SS needles prolonged procedure time without improving diagnostic yields and quality of histological specimens (qualitative number of lymphocytes, malignant cells and bronchial epithelia) [16]. However, cartilages in EBUS-TBNA specimens was not evaluated in the study, and it is not clear whether the results apply to CC needles yet. Compared with SS needles, sharper and harder CC needles may be able to separate the pre-existing tissue from any bronchial walls and cartilages entering the needle tip. Despite the same process of EBUS-TBNA in both groups in the present study, different amount of cartilage might be due to the use of stylets with CC

needles that could extract the cartilage without remaining in the needle tip. It is speculated that using inner stylet maybe more effective in CC needles than in SS needles.

CC is harder than SS, and the wall of CC needles are thinner than that of SS needles, allowing needles with the same gauge and larger inner diameter at the tip (Fig. 1C and D). In theory, needles with wider inner diameter should be more suitable for getting bigger core tissue sampling; however, it is controversial whether using 21-gauge SS needles improve diagnostic yields in the previous studies that compared 21-gauge with 22-gauge SS needles [13,21-24]. A prospective study showed that using 21-gauge SS needles resulted in greater blood contamination of the specimens [21]. In the present study, the number of inadequate specimens that contained only blood clot was no greater with the CC needles, which have a wider inner diameter. Using sharper and thinner metal needles may be more important for adequate tissue sampling than using thicker gauge needles.

Major EBUS-TBNA related complications such as, bleeding, infections, including mediastinitis, pneumonia and pericarditis, and pneumothorax have been reported [10,25-28], but complications were indifferent between the two groups. A recent Japanese multiple center survey reported that needle-related needle breakage was a rare side effect (0.2%, 15/7345 cases) rather than the technical event [25]. All reported broken needle tips were made of SS [29-33], and using made up of metals harder than SS may prevent unexpected complications due to needle breakage.

There are several limitation associated with use of CC needles. First, the hardness of the needle material such as CC limits the flexibility of the bronchoscope and performing EBUS-TBNA. Second, the CC needle has a maximum extension of 60 mm from the bronchoscope and enables easier and smoother puncturing compared with that by SS needle, however, it considerably increases the risk of erroneous puncture. It is essential to continuously and carefully observe the tip of the needle on the ultrasound images.

In addition, this study had several limitations. First, this was a retrospective study conducted in a single institution with relatively small number of participants. Second, direct and strict comparisons with two types of needles could not be examined because it was impossible to perform EBUS-TBNA to the same lesion by the same bronchoscopist with each type of needle. Prospective, multi-center, randomized trials are needed to confirm the utility and safety of CC needles in EBUS-TBNA.

## Conclusions

This study demonstrated that more adequate EBUS-TBNA specimens can be obtained with CC needles than with SS needles. Tissue sampling has become increasingly more important with the advent of multiple gene mutations targeting and immunohistochemical analysis for suitable therapies in cancer patients. Further studies are necessary to establish the best puncture needles for obtaining tissue specimens essential for treatment selection.

# Abbreviations

EBUS, endobronchial ultrasound; EBUS-TBNA, endobronchial ultrasound-guided transbronchial needle aspiration

# Declarations

## Ethics approval and consent to participate

The Institutional Review Board of Kasukabe Medical Center (IRB no: 2017-013) approved this study without the need for informed consent.

## Consent for publication

Not applicable.

## Availability of data and materials

The dataset supporting the conclusions of this article is presented within the article. Detailed clinical dataset is not available to protect the privacy and confidentiality of research subjects.

## Competing Interests

The authors declare that they have no competing interests.

## Funding

None declared.

## Author's contributions

KU designed the overall study and analysed the data. AK sufficiently contributed to the gathering, interpretation and organisation of data. All authors have read and approved the final manuscript.

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## Tables

**Table 1.** Baseline characteristics of the patients and lesions compared between the two groups who underwent EBUS-TBNA

Characteristics	SS needle	CC needle	<i>P</i> <sup>a</sup>
Patients, n	38	39	-
Male/female	29/9	28/11	0.80
Age, years (median, range)	73 (45-85)	79 (49-85)	0.56
Primary disease			
Malignant/benign	33/5	34/5	1.0
Punctured lesions, n	41	47	-
Size, short axis			
Median, mm (range)	17 (6-61)	17 (7-65)	0.41
Size, long axis			
Median, mm (range)	27 (7-82)	27 (9-69)	0.39
Location			
Paratracheal (2R, 2L, 4R, 4L)	15	21	0.093
Subcarinal (7)	11	20	
Hilar (10R, 10L)	1	0	
Interlobar and lobar (11s, 11i, 11L)	8	3	
Central parenchymal	6	3	

Data are presented as number or median (range).

<sup>a</sup> Calculated using Fisher's exact test or the Mann-Whitney *U* test.

EBUS-TBNA, endobronchial ultrasound-guided transbronchial needle aspiration; SS, stainless steel; CC, cobalt chromium.

**Table 2.** Final diagnoses of the target lesions investigated by EBUS-TBNA with the two types of needle

Final diagnosis	SS needle (41 lesions)	CC needle (47 lesions)	<i>P</i> <sup>a</sup>
Malignancy	33 (80.5)	39 (83.0)	0.79
Adenocarcinoma	14 (34.1)	14 (29.8)	
Squamous cell carcinoma	5 (12.2)	9 (19.1)	
Small cell lung cancer	7 (17.1)	9 (19.1)	
Large cell carcinoma	0 (0.0)	1 (2.1)	
NSCLC, not otherwise specified	3 (7.3)	3 (6.4)	
Metastatic tumor	2 (4.9)	3 (6.4)	
Mesothelioma	1 (2.4)	0 (0.0)	
DLBCL	1 (2.4)	0 (0.0)	
Benign	8 (19.5)	8 (17.0)	
Sarcoidosis	1 (2.4)	2 (4.3)	
Reactive lymphadenopathy	0 (0.0)	1 (2.1)	
Bronchogenic cyst	1 (2.4)	0 (0.0)	
Others	6 (14.6)	5 (10.6)	

Data are presented as number (percentage).

<sup>a</sup> Calculated using Fisher's exact test.

EBUS-TBNA, endobronchial ultrasound-guided transbronchial needle aspiration; NSCLC, non-small cell lung cancer; DLBCL, diffuse large cell B-cell lymphoma; SS, stainless steel; CC, cobalt chromium.

**Table 3.** Classification of the histological specimens obtained by EBUS-TBNA with the two types of needle

Category	SS needle (121 punctures)	CC needle (145 punctures)	<i>P</i> <sup>a</sup>
□, Diagnostic	71 (58.7)	103 (71.0)	0.039
□, Non-diagnostic	38 (31.4)	30 (20.7)	
□, No specimen	12 (10.0)	12 (8.3)	

Data are presented as number (percentage).

<sup>a</sup> Calculated using Fisher's exact test,  $P = 0.039$  across the sampling yield of histological specimens (□ vs. □ and □) in each needle group.

EBUS-TBNA, endobronchial ultrasound-guided transbronchial needle aspiration; SS, stainless steel; CC, cobalt chromium.

**Table 4.** Evaluations of the histological specimens obtained by EBUS-TBNA using the two types of needle

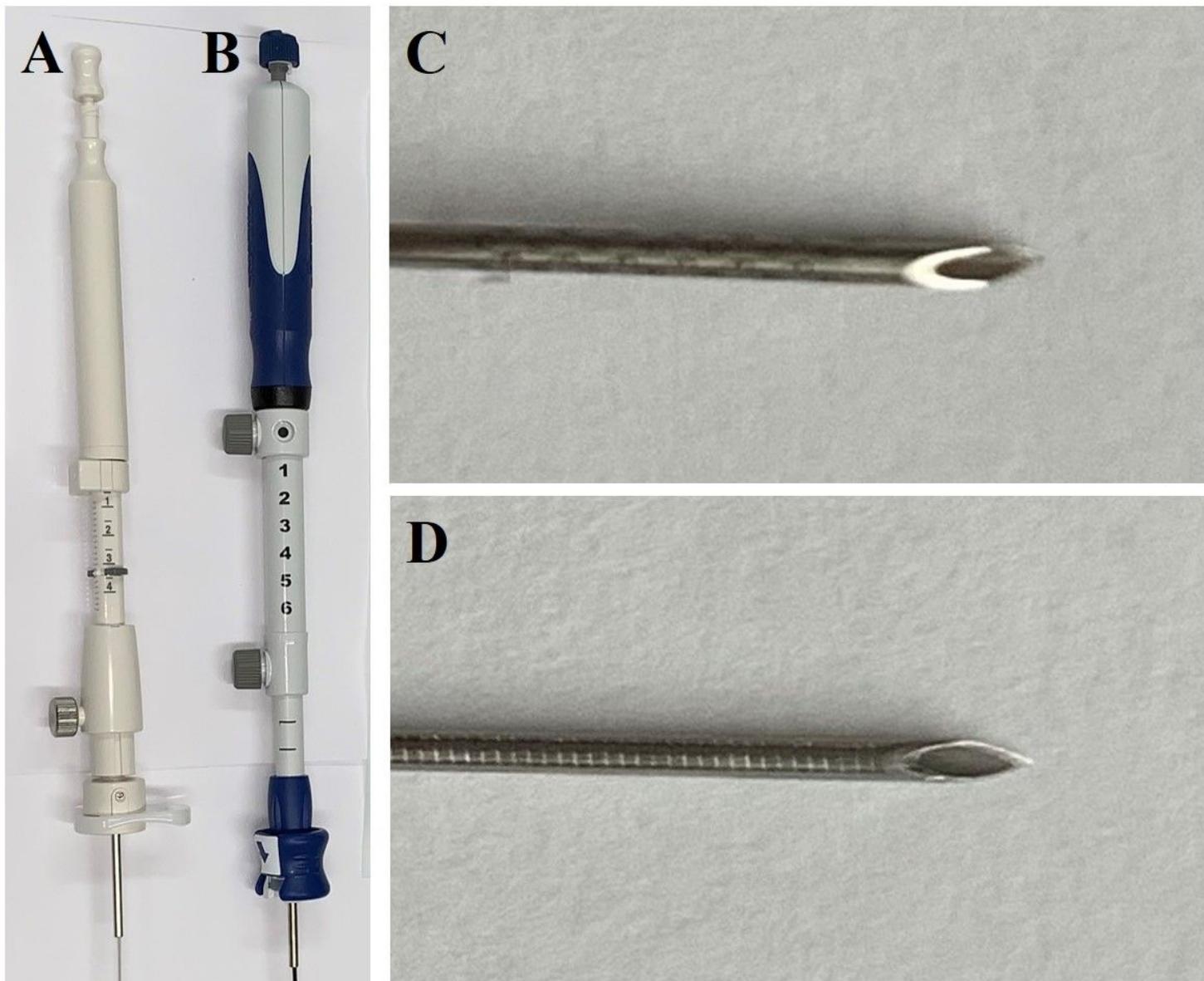
Evaluated histological findings	SS needle (121 punctures)	CC needle (145 punctures)	<i>P</i> <sup>a</sup>
Blood clot only	9 (7.4)	9 (6.2)	0.81
Containing cartilage	20 (16.5)	11 (7.6)	0.034
Cartilage only	8 (6.6)	2 (1.4)	0.047

Data are presented as number (percentage).

<sup>a</sup> Calculated using Fisher's exact test.

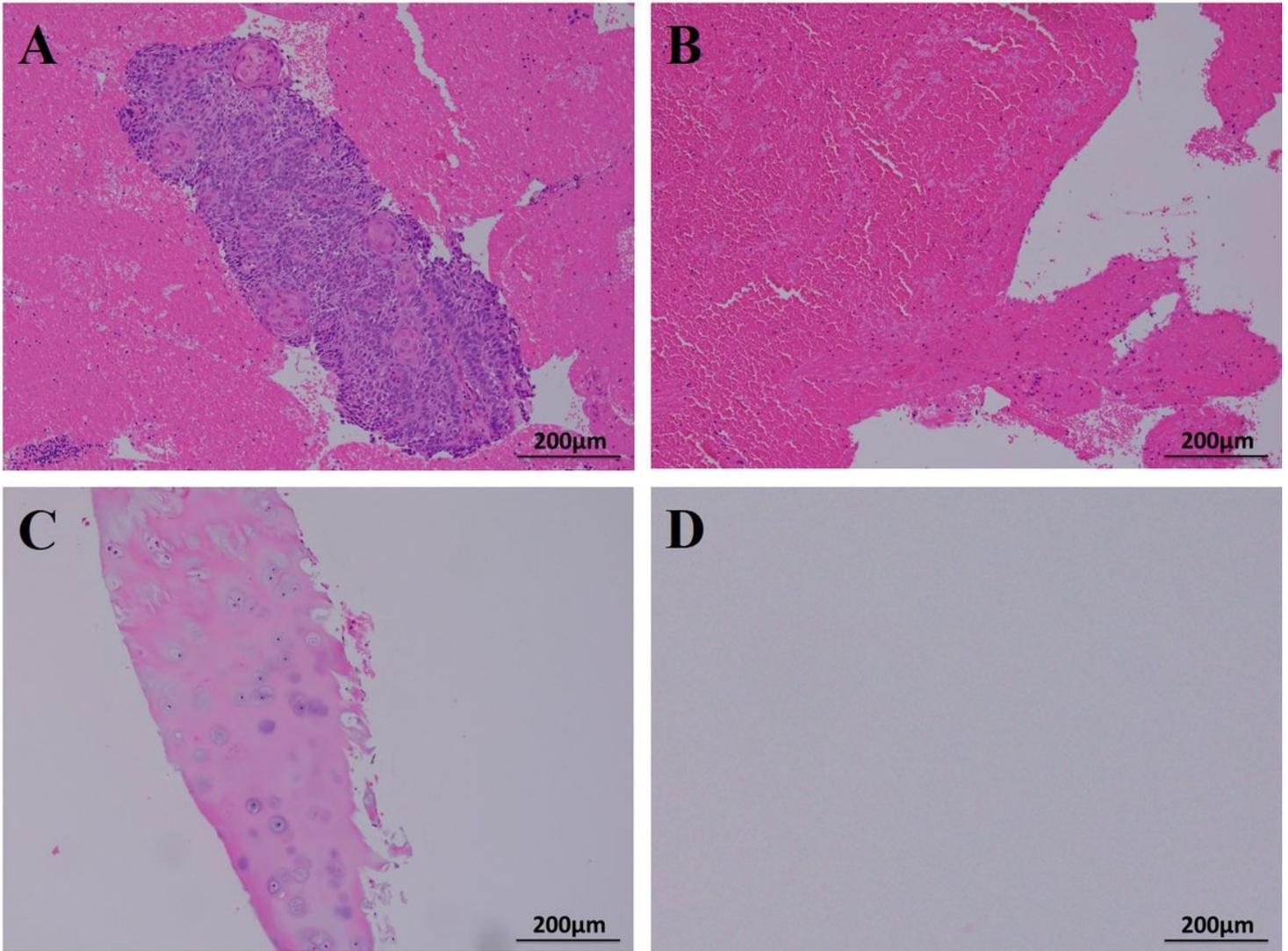
EBUS-TBNA, endobronchial ultrasound-guided transbronchial needle aspiration; SS, stainless steel; CC, cobalt chromium.

## Figures



**Figure 1**

The two 22-gauge needles for endobronchial ultrasound-guided transbronchial needle aspiration compared in this study. (A) Stainless steel needle (Vizishot® NA-201SX-4022, Olympus, Tokyo, Japan). (B) Cobalt chromium needle (Expect™ Pulmonary E00558220, Boston Scientific Corporation, Natick, MA, USA). (C) Tip of the stainless steel needle. (D) Tip of the cobalt chromium needle.



**Figure 2**

Categorization of the histological specimens. (☒) Specimen of squamous cell carcinoma (A), categorized as 'diagnostic'. (☒) Specimen containing only a blood clot (B) or cartilage (C), categorized as 'non-diagnostic'. (☒) Absence of samples (D), categorized as 'no specimen'. (Haematoxylin and eosin stain; original  $\times 100$ ).