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Novel thin bronchoscope with a 1.7-mm working channel for peripheral pulmonary lesions

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SHORT TITLE:

Thin bronchoscope for pulmonary lesions.

STATEMENT OF INTEREST

The prototype thin bronchoscope was loaned to the authors by Olympus Ltd., Tokyo, Japan for the duration of this study. None of the authors has any financial stake in Olympus Ltd.

ABSTRACT

We evaluated the diagnostic utility of a novel thin bronchoscope with a 1.7-mm working channel for peripheral pulmonary lesions.

A total of 118 patients were included in this prospective study. Bronchoscopic examination using a 5.9-mm standard bronchoscope was first performed. If there was no visible endobronchial lesion, then transbronchial biopsies were performed with a 1.5-mm biopsy forceps under fluoroscopic guidance and washing with 10-20 ml of saline solution, using a prototype 3.5-mm thin bronchoscope with a 1.7-mm working channel.

Endobronchial lesion was visualized with the standard bronchoscope in 16 patients, and residual 102 patients underwent biopsies with the thin bronchoscope. The mean bronchus level reached with the standard bronchoscope and the thin bronchoscope was 2.3th and 4.3th, respectively. Endobronchial abnormality was revealed with the thin bronchoscope in a further 14 patients. Diagnostic material was obtained in 50

of 68 patients (74%) with malignant disease and 18 of 30 patients (60%) with benign disease. Four patients did not return to follow-up. The diagnostic yield was 57% even in lesions < 20 mm. There were no major complications.

Bronchoscopy using a 3.5-mm thin bronchoscope with a 1.7-mm working channel is useful and safe for the diagnosis of peripheral pulmonary lesions.

KEYWORDS: Bronchoscopy, lung cancer, peripheral pulmonary lesions, thin bronchoscope, transbronchial biopsy, ultrathin bronchoscope

Localized peripheral pulmonary lesions are commonly encountered in clinical practice and frequently require tissue diagnoses to project a treatment plan. In the diagnosis of such lesions, bronchoscopy under fluoroscopic guidance has come into wide use as a simple, safe and readily available sampling technique. However, the diagnostic yield of bronchoscopy for peripheral pulmonary lesions has been reported to be limited, and so the usefulness of conventional bronchoscopy is controversial [1-3].

Innovation in technology has permitted the development of some promising bronchoscopes including those thinner than the conventional types. A preliminary study suggested that the use of a thin bronchoscope (BF-3C40, 3.3-mm distal end diameter, 1.2-mm working channel diameter; Olympus; Tokyo, Japan) as an adjunct instrument to a standard bronchoscope increases the diagnostic yield by providing an accurate pathway to the peripheral pulmonary lesions [4]. However, transbronchial biopsy (TBB) using currently available biopsy forceps for the 1.2-mm working channel was not performed in the study, and so the role of the thin bronchoscopy as a single method for diagnosing peripheral pulmonary lesions remains to be clarified. Additionally, several investigators

have indicated that the small-caliber working channel (1.2 mm) of now available thin bronchoscopes has the limitation of insufficient specimen collection [5-7]. Therefore, the clinical application of thin bronchoscopy for examining peripheral pulmonary lesions in adult patients has been quite limited.

Thus, the use of a thin bronchoscope with a larger working channel for examining peripheral pulmonary lesions seems to be promising. The aim of this study was to assess the utility of a novel thin bronchoscope with a 1.7-mm working channel in the diagnosis of peripheral pulmonary lesions.

MATERIALS AND METHODS

Patients

This prospective study was approved by the institutional review board of our hospital and informed consent was obtained from all patients. Between March 2005 and March 2006, 118 patients with localized peripheral pulmonary lesions, such as a solitary

pulmonary nodule, a pulmonary mass or a localized infiltrate, referred for diagnostic bronchoscopy were enrolled. Patients with diffuse pulmonary lesions were excluded.

Procedures

All bronchoscopic procedures were performed using conscious sedation with bolus IV midazolam and topical anesthesia with lidocaine by staff pulmonologists or supervised pulmonary residents of our institution. A 7.5-mm inner diameter endotracheal tube was placed transorally under bronchoscopic control using a standard bronchovideoscope (BF-240 or BF-1T260, 5.9-mm distal end diameter; Olympus; fig. 1), as in the method of Ikeda [8] who developed the flexible bronchoscope. Then bronchoscopy to examine the endobronchial region was performed in the standard fashion. If an endobronchial lesion (*eg,* exophitic endobronchial mass, submucosal spread, or a peribronchial tumor causing extrinsic compression) was detected, tissue sampling was performed using the standard bronchoscope and the examination was then terminated. If no endobronchial lesion was observed, we exchanged the standard bronchoscope for a thin bronchoscope (XBF-3B40Y1; Olympus, 3B40; fig. 1) for examining peripheral pulmonary lesions. The

3B40 bronchofiberscope has a 3.5-mm distal end diameter, 1.7-mm working channel diameter, 180°up and 130°down angulation, 90°field of view and 2~50-mm depth of field. The 3B40 was advanced toward the bronchus most likely leading to the lesion under direct vision. After the 3B40 was inserted and wedged into the peripheral bronchus as far as possible, TBB using a 1.5-mm forceps (FB-32D or XBO1-951, Olympus) was performed under fluoroscopic guidance. Eight biopsy specimens were taken from each lesion, and each specimen was then transferred into separate containers filled with formalin for histologic examination. After TBB, washing in the corresponding bronchus was performed with 10-20 ml of saline solution. The retrieved washing fluid was submitted for cytologic examination and culture. Other procedures such as brushing, curettage or needle aspiration biopsy for the target lesion were not performed in the same setting. A chest radiograph was obtained routinely to identify pneumothorax after the procedures. The number of bronchial generations of the standard or thin bronchoscope inserted was recorded. The number of the bronchial generation as defined by the Classification of Lung Cancer, First English Edition, 2000, The Japan Lung Cancer Society, was as follows: 0, main bronchi; I, lobar bronchi; II, segmental bronchi (*eg,* B^1,

B^2); III, subsegmental bronchi (*eg,* B^1a, B^1b); IV, subsubsegmental bronchi (*eg,* B^1ai, B^1aii); and V, subsubsubsegmental bronchi (*eg,* B^1aiα, B^1aiβ).

Diagnosis

All malignant diagnoses, except that of a patient with peripheral T-cell lymphoma in whom the pulmonary lesion disappeared after chemotherapy, were confirmed pathologically. The benign diagnoses were established by surgical procedure, microbiological analysis including tuberculosis or nontuberculous mycobacteriosis, or clinical follow-up. The lesions which obviously diminished or disappeared during the follow-up period were considered to be inflammation. Other benign diagnoses were confirmed by radiological size stability and clinical compatibility during the follow-up period for at least 18 months after bronchoscopy.

Statistical Analysis

Means and percentages were presented as appropriate. The accuracies were calculated using the standard definitions. Statistical analyses were performed using a statistical

software program (JMP; SAS Institute; Cary, NC). Results were considered statistically significant when the p value was less than or equal to 0.05.

RESULTS

Endobronchial lesions were visualized with the standard bronchoscope in 16 patients, and the other 102 patients underwent biopsies with the 3B40. Four patients were lost to follow-up. Thus, a total of 98 patients (55 men and 43 women; mean age, 65.1 years; range, 36 to 82 years) with peripheral pulmonary lesions (median size, 30.5 mm; mean size, 34.3 $\pm$ 16.8 mm; range, 11 to 76 mm) were included in the final analysis. The characteristics of the patients are given in table 1.

The final diagnoses and the results of thin bronchoscopy are shown in table 2. Diagnostic material was obtained by the 3B40 in 50 of 68 patients (74%) with malignant disease, 18 of 30 patients (60%) with benign disease and overall 68 of 98 patients (69%). TBB was diagnostic in 49 patients (72%) with malignant disease and 15 patients (50%) with benign disease, whereas cytologic specimen of washing was positive in 11 patients (16%) with

malignant disease and culture of washing provided diagnosis in 9 patients (30%) with benign disease. Washing alone provided diagnosis in 4 patients (1 adenocarcinoma, 2 tuberculosis, and 1 nontuberculous mycobacteriosis). The sensitivity, specificity, negative predictive value, positive predictive value and accuracy of the thin bronchoscopy for diagnosing malignancy were 74%, 100%, 63%, 100% and 82%, respectively.

The diagnostic yield of thin bronchoscopy related to the lesion size, which was determined by measuring the greatest diameter on CT, is shown in table 3. Diagnostic yield of thin bronchoscopy for the lesions < 20 mm and ≥ 20 mm in size was 57% (13 of 23) and 73% (55 of 75), respectively. The diagnostic yield was not significantly different in terms of the lesion size. ($p = 0.13$, χ^2 test).

The 3B40 could be inserted into more distal bronchi compared to the standard bronchoscope (mean, 4.3 ± 1.0 vs 2.3 ± 1.0 generations; $p < 0.001$, paired *t* test; fig. 2). An endobronchial abnormality that could not be visualized with a standard bronchoscope

was revealed with the 3B40 in 14 patients (14%; fig. 3). Diagnostic yield was not affected by the location of the lesion ($p = 0.68$, χ^2 test; table 4).

There were no significant complications such as major bleeding or pneumothorax.

DISCUSSION

Our results indicate that bronchoscopy using a 3.5-mm thin bronchoscope with a 1.7-mm working channel is useful enough as a single method for the diagnosis of peripheral pulmonary lesions. The thin bronchoscope can enter a further 2 distal generations of bronchi from the bronchi reached by a 5.9-mm standard bronchoscope, and is thus likely to increase the diagnostic yield. The yield of thin bronchoscopy was as high as 69%, and 57% even in lesions < 20 mm.

Flexible bronchoscopy with or without fluoroscopic guidance has been commonly used for evaluating various pulmonary lesions for over the past three decades [8, 9]. For endoscopically visible central lesions, it is a recommended procedure because of its high

diagnostic yield [10]. However, the role of the conventional procedure for evaluating peripheral pulmonary lesions is controversial [1-3]. The diagnostic yield for peripheral pulmonary lesion varies widely in the literature between 20% to 80% and depends on the size of the lesion [11-15]. In a recent review article [10], the sensitivity of conventional bronchoscopy for peripheral bronchogenic carcinoma < 20 mm and > 20 mm in size was reported to be 34% and 63%, respectively. The conventional bronchoscope can be inserted only as far as the segmental or subsegmental bronchus. Therefore, inserting and advancing instruments such as a biopsy forceps or cytology brush into the angled bronchial branch is often difficult. Thin bronchoscopy has a distinct advantage of maneuverability for selecting a target bronchus likely leading to a lesion. Moreover, a lesion invisible to standard bronchoscope was visualized with the 3B40 in 14% of patients. In the present study, the sensitivity of thin bronchoscopy in patients with malignant lesions < 20 mm and $\underline{\geq}$ 20 mm in size was 77% and 73%, respectively. While our study was not designed specifically to compare the diagnostic yields of thin and conventional bronchoscopy, thin bronchoscopy seems to improve the diagnostic yield over conventional bronchoscopy.

Although the application of a thin bronchoscope in adults is not a novel idea [8, 16], only a few small studies have addressed the role of thin bronchoscope for evaluating localized peripheral pulmonary lesions [4, 6, 17-19]. The 3.3-mm thin bronchoscope (BF-3C40) was reportedly a useful adjunct to conventional bronchoscopy in the diagnosis of peripheral pulmonary lesions [4]. Seventeen patients with peripheral lesion underwent bronchoscopy using the BF-3C40 followed by the use of a standard bronchoscope. The diagnostic yield of TBB with standard bronchoscope under fluoroscopic guidance that followed the same bronchial route to the lesion established by the BF-3C40 was 65% (11 of 17) in all patients examined, and 70% (7 of 10) in patients with lesions < 30 mm in size. Direct visualization of the lesion was achieved with the BF-3C40 in 24% of patients (4 of 17). The major technical limitation of the method may be the difficulty in maneuvering the biopsy forceps through the standard bronchoscope to follow the same bronchial route explored with the thin bronchoscope. Unfortunately, TBB using the BF-3C40 and a biopsy forceps for a 1.2-mm working channel was not performed in the study, and so the role of thin bronchoscopy alone was not assessed. Another study using a 2.8-mm ultrathin

bronchoscope with a 1.2-mm working channel demonstrated that TBB under fluoroscopic guidance using an ultrathin bronchoscope provided a higher diagnostic yield than that using a standard bronchoscope (60% vs 54%) [6]. Nevertheless, the authors described ultrathin bronchoscopy as a useful adjunct but not an alternative to conventional bronchoscopy, because sufficient material for histologic specimen can not always be obtained with forceps for a 1.2-mm working channel. Most of the thin bronchoscopes now available incorporate a 1.2-mm working channel, and various instruments such as a biopsy forceps or a cytology brush that can be passed through the 1.2-mm working channel are available. However, the small-caliber working channel or miniaturized instruments have some functional drawbacks including poor suction capability or inadequate specimen collection [5-7]. Therefore, the clinical application of thin or ultrathin bronchoscopy for diagnosing peripheral pulmonary lesions has been limited. The major advantages of the 3B40 over conventional thin bronchoscopes with a 1.2-mm working channel are its adequate suction performance or larger instrument compatibility due to the 1.7-mm working channel incorporated. The forceps for a 1.7-mm channel is stouter and more maneuverable than the forceps for a 1.2-mm channel. We

were satisfied with the size and quality of the sampling specimen using the forceps for pathological examination. The 3B40 can thus be a useful alternative to a standard bronchoscope for examining peripheral pulmonary lesions.

The diagnostic yield of washing for peripheral malignant lesions using the standard bronchoscopes has been reported to range from 13% to 52% [14, 20-22], and the usefulness of cytologic examination of bronchial washings in addition to TBB is controversial [23]. Our yield (16%) of bronchial washing using the thin bronchoscope seems to be low. It could be because of the low retrieval of instilled saline during our procedures. The small peripheral bronchi with soft walls readily caused the thin bronchoscope to collapse under bronchoscopic suction. Therefore, instilled saline tends to be trapped in the more peripheral bronchi. We cannot abandon this safe, inexpensive and minimal time-consuming procedure during thin bronchoscopy, because the cytological specimen from washing was the sole diagnostic specimen in one patient with adenocarcinoma. However, technical improvements, such as using larger amounts of

saline solution [22] or applying low pressure suction, would be needed to increase the yield.

Recently, in an effort to increase the diagnostic yield of bronchoscopy for peripheral pulmonary lesions, several ancillary technologies have been proposed such as multiplanar reconstruction (MPR) [24], electromagnetic navigation bronchoscopy (ENB) [25-30], virtual bronchoscopic navigation [5, 7], CT fluoroscopy [31, 32] or endobronchial ultrasound (EBUS) [30, 33-38] as well as thin bronchoscopy. The effects of these modalities during the bronchoscopy are as follows: (1) Mapping and navigation, (2) Arrival verification of bronchoscopic instruments, or (3) Bronchoscopic maneuverability.

The selection of the most appropriate bronchus for TBB from the preprocedural static images such as chest X-ray or standard CT imaging is often difficult. Modifications in CT technology have permitted the development of the helical CT with MPR that provides every desired axis image of the lung. MPR imagings can be used as a bronchial map that

allows selection of an appropriate bronchial route to the peripheral pulmonary lesions. Additional MPR and rapid on-site evaluation using ultrafast Papanicolaou stain was reported to increase the diagnostic yield of bronchoscopy for the peripheral pulmonary lesions from 58% to 91% [24]. More recently, several navigation systems have been developed as a guiding tool to reach the target lesions. An electromagnetic navigation system (superDemension/Bronchus, superDimension Ltd; Hertzliya, Islael), that creates an electromagnetic field around the chest, and localizes a steerable navigation catheter with an electromagnetic sensor overlaid upon previously acquired CT images, is a useful method for assisting in the localization of the peripheral pulmonary lesions during bronchoscopy [25]. The diagnostic yield of ENB for peripheral pulmonary lesions has been reported to range from 59 to 74% [26-30]. Furthermore, several investigators [27, 28, 30] indicated that the diagnostic yields of ENB were independent of lesion size or location. The virtual bronchoscopic navigation system (Olympus) produces virtual bronchoscopy (VB) images of the bronchus leading to the lesions automatically that are reconstructed from helical CT data [7]. The bronchoscope is advanced to the target lesion comparing the VB images and actual bronchoscopic images simultaneously, so

bronchoscopic visibility, insertability and maneuverability in the peripheral bronchi are important during the procedure. A few pilot studies [5, 7] have shown the usefulness of ultrathin bronchoscopy with this system for evaluating peripheral pulmonary lesions. The diagnostic yield of ultrathin bronchoscopy using this system, X-ray fluoroscopy, and/or CT fluoroscopy for the peripheral pulmonary lesions, reportedly averaged 65% to 82% [5, 7], irrespective of the size of the lesions. Fluoroscopy-guided TBB is a common and simple bronchoscopic procedure for patients with peripheral pulmonary lesions. However, the two-dimensional image of fluoroscopy produces overlapping structures or instruments. Thus, accurately confirming that the forceps has reached the lesion is often difficult, even if the positions of the instrument and the target lesion are confirmed three-dimensionally, either by rotating the patient or the arm of a C-arm fluoroscope. CT fluoroscopy or EBUS allows precise verification of whether a bronchoscopic tool has reached the lesions, even if fluoroscopically invisible [38]. A comparative study [31] demonstrated that the diagnostic yield of bronchoscopy under CT fluoroscopic guidance was higher than that of X-ray fluoroscopic guidance (62% vs 53%). However, CT-fluoroscopic guidance has the disadvantage of excessive radiation exposure for

patients and staff. To overcome this disadvantage, the usefulness of dose reduction CT fluoroscopy has been reported [32]. EBUS using a radial probe is also a useful adjunct to conventional bronchoscopy to increase the diagnostic yield for peripheral pulmonary lesions. The diagnostic yield of EBUS has been reported to range from 58% to 80% [30, 33-38]. This method is particularly useful for small lesions, and provides a high diagnostic yield of 70% even for fluoroscopically invisible lesions [38]. A recent lung cancer guideline [10] recommends bronchoscopy with EBUS as available for the diagnosis of small peripheral pulmonary lesions.

Interestingly, these modalities were likely to be complementary in increasing the diagnostic yield. A randomized controlled trial [30] demonstrated that the diagnostic yield of EBUS, ENB and the combination of EBUS and ENB for peripheral pulmonary lesions were 69%, 59% and 88%, respectively. Although a guide catheter with double-hinged curette [34-36] or a dedicated steerable device [25-30] has often been used to overcome the difficulties of introducing and advancing the biopsy instrument to the area of interest, a thin bronchoscope with good bronchial selectivity and smooth

maneuverability in the peripheral airway may perform the procedure easily and simply. The combination of thin bronchoscopy with the 3B40 and such newer imaging guidance techniques may enhance the diagnostic yield.

Although it is usually mild, the complication rate of pneumothorax and bleeding related to the TBB with standard forceps has been reported to be 1-5% and 9%, respectively [39]. Fortunately, such complications were not observed during the study periods. The size of the forceps for the 3B40 is slightly smaller than that for the standard bronchoscope with a 2.0-mm working channel. Although complications may occur even if a small forceps is used [40], TBB with 3B40 and the dedicated forceps may reduce the risk or the severity of complications such as pneumothorax or bleeding. Furthermore, a recent study suggested thin bronchoscopy with the 3B40 was better tolerated than with standard bronchoscopy [41].

In conclusion, bronchoscopy using a 3.5-mm thin bronchoscope with a 1.7-mm working channel is useful and safe for the diagnosis of peripheral pulmonary lesions. Moreover, it

is a useful alternative to a standard bronchoscope for examining peripheral pulmonary lesions. In future applications, in combination with imaging guidance techniques such as EBUS or bronchoscopic navigation, the yield with this procedure may be even further enhanced.

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TABLE 1 Characteristics of the patients and lesions

Patients n	98
Gender M/F	55/43
Age, yr	65.1 ± 10.9
Current smokers %	36.7
Lesion size, mm	34.3 ± 16.8
< 20 mm/≥ 20 mm	23/75
Location	
Right upper lobe	35
Right middle lobe	5
Right lower lobe	24
Left upper lobe	18
Lingula	5
Left lower lobe	11

Data are presented as n or mean ± SD unless otherwise stated.

TABLE 2 Final diagnosis and results of thin bronchoscopy in 98 patients

Diagnosis	Patients in trial n	Patients with diagnosis by thin bronchoscopy n (%)
Malignant		
Adenocarcinoma	37	28 (76)
Squamous cell carcinoma	15	13 (87)
Large cell carcinoma	3	2 (67)
Bronchiolo-alveolar carcinoma	2	0 (0)
Non-small cell carcinoma	6	4 (67)
Small cell carcinoma	2	1 (50)
Metastasis (colon cancer)	1	1 (100)
Malignant lymphoma	2	1 (50)
Benign		
Tuberculosis	6	4 (67)
Nontuberculous mycobacteriosis	4	4 (100)

Pneumoconiosis	2	2 (100)
Bacterial pneumonia	2	2 (100)
Organizing pneumonia	1	1 (100)
Cryptococcosis	1	1 (100)
Amyloidosis	1	1 (100)
Pulmonary abscess	1	0 (0)
Hamartoma	1	0 (0)
Wegener's granulomatosis	1	0 (0)
Inflammation	6	3 (50)
Benign	4	0 (0)
Total	98	68 (69)

TABLE 3 Diagnostic yield of thin bronchoscopy by lesion size

	Number of lesions diagnosed / lesions examined (%)		
Lesion size	**Malignant**	**Benign**	**Total**
< 20 mm	10/13 (77)	3/10 (30)	13/23 (57)
≥ 20 mm	40/55 (73)	15/20 (75)	55/75 (73)
Total	50/68 (74)	18/30 (60)	68/98 (69)

$p = 0.13$, χ^2 test between the diagnostic yield for the lesions < 20 mm and ≥ 20 mm in size.

TABLE 4 Diagnostic yield and inserted bronchial generation of thin bronchoscopy in relation to bronchopulmonary segments

	Bronchial generation	**Number of lesions diagnosed / lesions examined (%)**		
Segments	**inserted**	**Malignant**	**Benign**	**Total**
RUL	4.5 ± 1.0	17/22 (77)	8/13 (62)	25/35 (71)
RML	4.2 ± 1.3	3/4 (75)	0/1 (0)	3/5 (60)
RLL	4.0 ± 0.8	8/14 (57)	6/10 (60)	14/24 (58)
LUL	4.4 ± 1.1	12/17 (71)	1/1 (100)	13/18 (72)
Lingula	4.4 ± 1.1	2/3 (67)	2/2 (100)	4/5 (80)
LLL	4.5 ± 0.9	8/8 (100)	1/3 (33)	9/11 (82)

p = 0.68, χ^2 test across diagnostic yield in the locations of the lesions. RUL: right upper lobe; RML: right middle lobe; RLL: right lower lobe; LUL: left upper lobe; LLL: left lower lobe.

FIGURE LEGENDS

FIGURE 1. A comparison of bronchoscopes. Left: Standard bronchoscope with a distal end diameter of 5.9 mm and a working channel of 2.0 mm (BF-240); right: Thin bronchoscope with a distal end diameter of 3.5 mm and a working channel of 1.7 mm (XBF-3B40Y1).

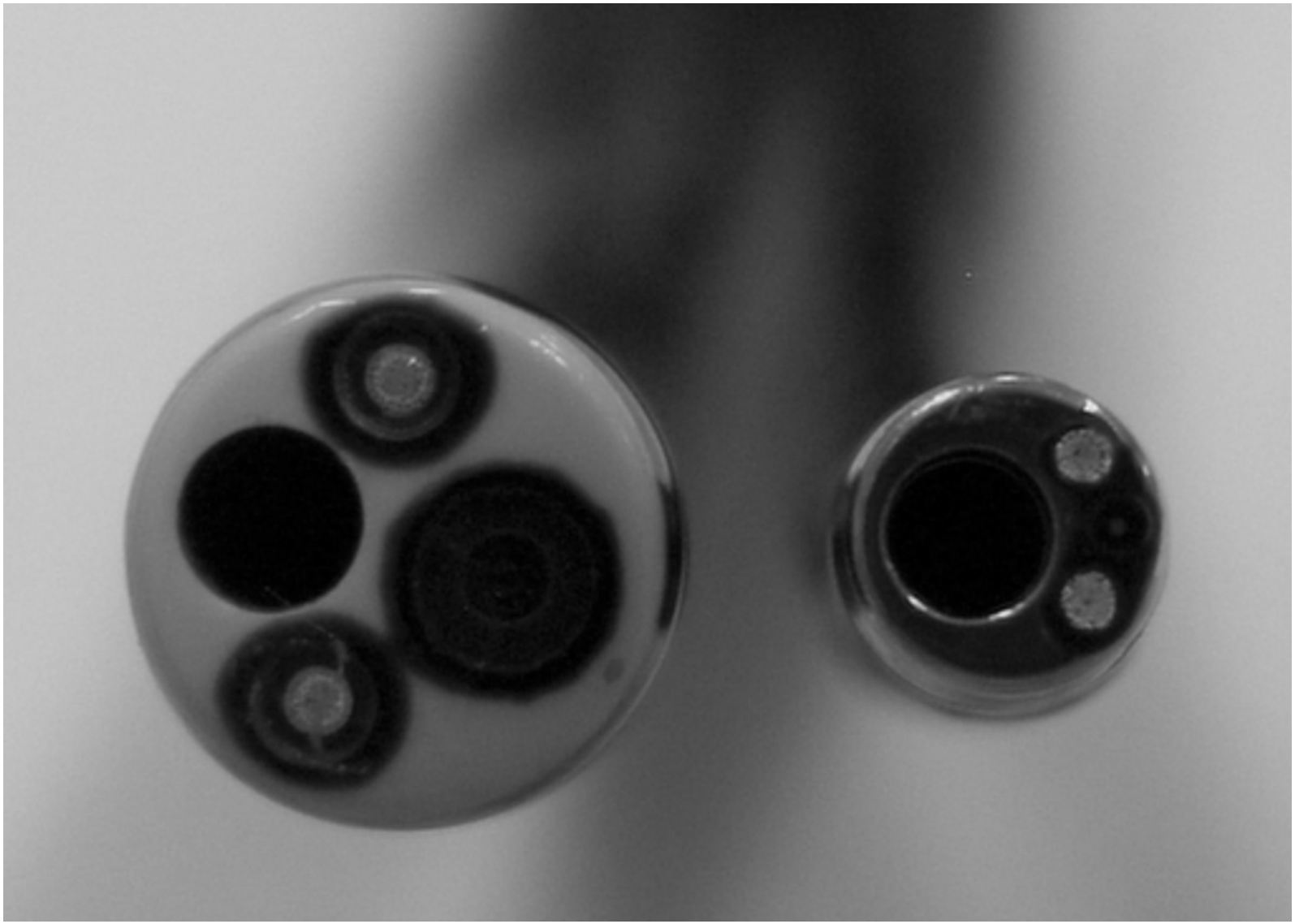


FIGURE 2. Fluoroscopic images of standard bronchoscope a) and XBF-3B40Y1 b).

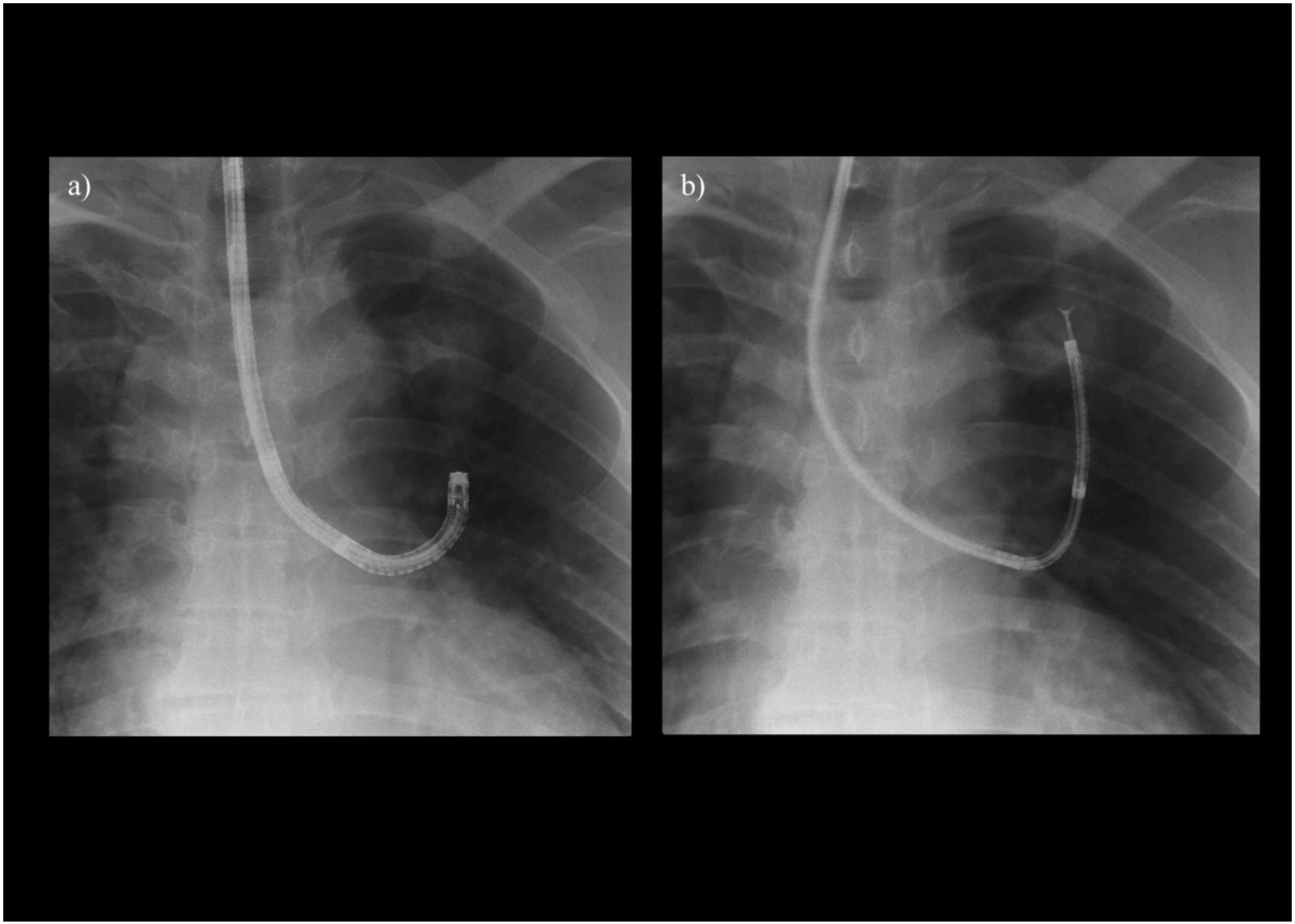
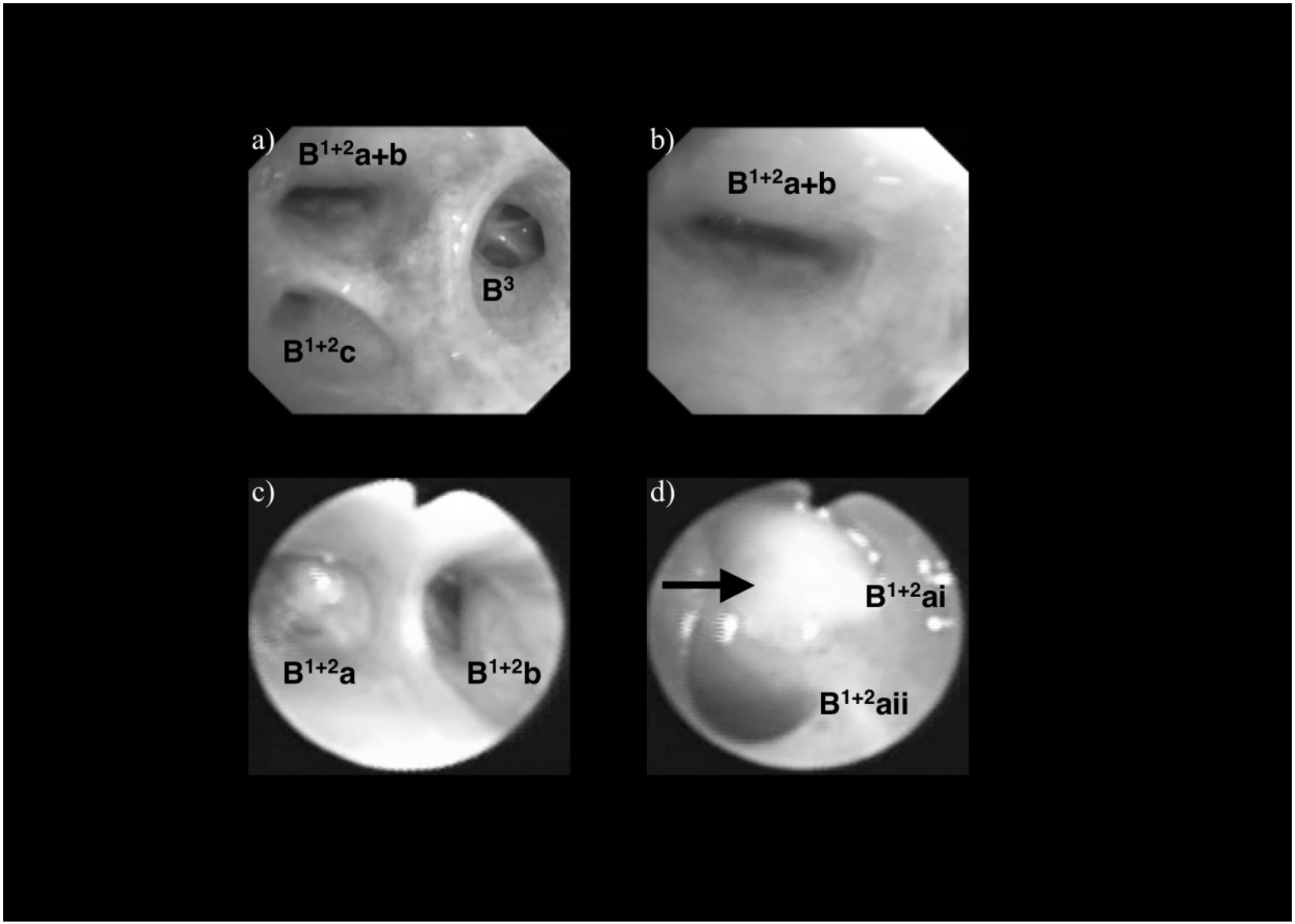

a)
b)

FIGURE 3. a) and b) Standard bronchoscopic views of left upper lobe bronchus. b) Standard bronchoscope could be inserted as far as subsegmental bronchus (B^{1+2}a+b). c) and d) Thin bronchoscopic views of more distal bronchi. d) Endobronchial tumor (adenocarcinoma; arrow) of the fourth generation bronchus (B^{1+2}ai) was revealed.


a)
B1+2a+b
B3
B1+2c
b)
B1+2a+b
c)
B1+2a
B1+2b
d)
B1+2ai
B1+2aii