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ORIGINAL ARTICLE

Use of electromagnetic navigation bronchoscopy in virtual-assisted lung mapping: the effect of on-site adjustment

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Abstract

Objective Conventional virtual-assisted lung mapping (VAL-MAP), also termed multi-spot preoperative bronchoscopic lung marking, necessitates post-mapping computed tomography (CT) to confirm the locations of dye markings. We hypothesized that electromagnetic navigation bronchoscopy (ENB) simplifies VAL-MAP by omitting post-mapping CT.

Methods Under general anesthesia, real-time navigation bronchoscopy was conducted using ENB to reach a site as close to the planned location as possible, and indigo carmine was injected. Initially, surgery was then performed (no-adjustment group; 5 lesions of 3 patients). Later, on-site adjustment was added before surgery (adjustment group; 4 lesions of 4 patients), in which the locational information of ENB was transferred to a radiology workstation to construct an adjusted three-dimensional image. The accuracy of each predicted marking location was graded based on intraoperative observation. After the analysis, 19 patients with 21 lesions underwent ENB VAL-MAP with on-site adjustment (practice set) to evaluate the surgical outcomes.

Results The accuracy of the predicted marking location was significantly higher in the adjustment than no-adjustment group (4.7 ± 0.7 vs. 3.4 ± 1.2, respectively; $P = 0.01$), especially among the markings for which the bronchoscope did not reach the planned location (4.5 ± 0.8 vs. 2.6 ± 0.5, respectively; $P = 0.004$). In the practice set, the lung map quality was satisfactory and the resection outcome was successful with a sufficient macroscopic resection margin in 19/21 lesions (90.5%).

Conclusion The ENB VAL-MAP quality was improved by adding on-site adjustment, achieving clinical outcomes similar to conventional VAL-MAP. The logistic challenge of post-mapping CT in conventional VAL-MAP can be partially overcome by ENB VAL-MAP with on-site adjustment.

Keywords Electromagnetic navigation bronchoscope · Virtual-assisted lung mapping · Localization · Dye marking

Introduction

Localization of small pulmonary nodules during sublobar lung resection is sometimes challenging, especially during minimally invasive thoracoscopic surgery. Multiple localization techniques with which to overcome this challenge have been reported, such as placing a hookwire [1], microcoil [2], and dye [3] by either computed tomography (CT)-guided percutaneous methods or bronchoscopic placement [4]. More recently, the use of electromagnetic navigation bronchoscopy (ENB) has been reported in preoperative dye localization [5, 6]. The advantage of this technology is real-time navigation through the bronchial tree to reach the target on an easy-to-use platform. The procedure can be performed during the same session of general anesthesia as the following surgery.

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Virtual-assisted lung mapping (VAL-MAP) is a relatively novel multi-spot bronchoscopic dye marking technique [7]. Unlike other localization techniques, VAL-MAP is characterized by placement of multiple marks (i.e., the lung “map”) on the lung, which makes it possible not only to localize a pulmonary nodule but also to set appropriate resection lines and acquire safe resection margins [8, 9]. VAL-MAP was demonstrated to be a highly safe, effective, and reproducible procedure in two prospective multicenter clinical trials in Japan [9, 10].

However, in the current VAL-MAP technique, the bronchoscopic marking procedure is conducted with sedation and local anesthesia, and a post-mapping CT scan is then performed to confirm the actual locations of the dye markings before surgery [7]. Importantly, despite the apparently heavy logistics, post-mapping CT is considered to be mandatory in the current VAL-MAP technique [11]. We demonstrated that the marking locations predicted by virtual bronchoscopy were dislocated from the actual markings depicted by post-mapping CT by an average of approximately 3 cm [11]. However, because the lung map can be adjusted based on the post-mapping CT scan reflecting the actual locations of the dye markings, surgery can be accurately performed. In other words, adjustment of the marking locations by post-mapping CT enables accurate surgery by showing adjusted post-mapping three-dimensional images almost identical to what would be observed during surgery [8].

We hypothesized that introduction of ENB to VAL-MAP may simplify the logistics by omitting post-mapping CT. In the present study, we developed a new technique of “on-site adjustment,” wherein the three-dimensional information obtained during real-time navigation is overlaid onto the digital imaging and communications in medicine (DICOM) data of the original CT images in another workstation, and an adjusted three-dimensional image reflecting the actual marking locations is then reconstructed. We herein present our early experience of ENB VAL-MAP with or without the on-site adjustment technique.

Methods

Patients

Patients were selected for preoperative VAL-MAP if the targeted lesion was expected to be hardly palpable and/or special attention was needed to determine the resection line. Patients who underwent VAL-MAP using ENB and subsequent surgery at the University of Tokyo Hospital from September 2017 to January 2019 were included in the study. The study was retrospectively conducted using the patient data collected for the study for VAL-MAP. The whole study was registered as UMIN 000008031 at the University Hospital Medical Information Network Clinical Trial Registry (http://www.umin.ac.jp/ctr/) and conducted under the approval of the ethics committee of the institute. Informed consent was obtained from each patient. The patients underwent a series of bronchoscopic procedures under general anesthesia (Fig. 1).

Mapping design and preparation

The lung map, which was composed of multiple dye markings, was designed using the “mapping mode” of a high-quality three-dimensional image analysis system (Synapse Vincent®; FujiFilm Medical, Tokyo, Japan) as previously described [8, 11]. In general, two-to-four marking locations

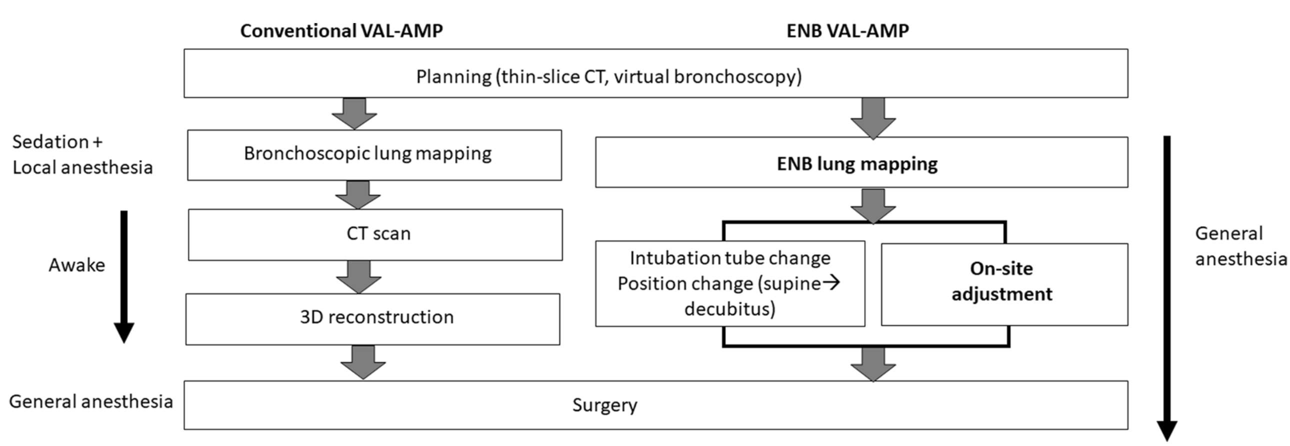

Fig. 1 Differences in procedural steps between conventional and ENB VAL-MAP. Steps of conventional VAL-MAP (left) and ENB VAL-MAP (right) are shown. Note that, in ENB VAL-MAP, most of the steps are conducted in a single general anesthesia session without a post-mapping CT scan. *VAL-MAP* virtual-assisted lung mapping, *ENB* electromagnetic navigation bronchoscopy, *CT* computed tomography, *3D* three-dimensional

were selected among marking candidates to indicate appropriate resection lines or the location of the tumor.

The locational information of each planned marking was displayed on axial CT images of Synapse Vincent®. This information was then manually transferred to the ENB system (superDimension™ navigation system; Medtronic, Minneapolis, MN), wherein a "peripheral target" was selected for the locational information, and then, the pathway leading to the target (i.e., the planned marking location) was semiautomatically determined. This pathway was usually identical to the pathway selected by Synapse Vincent®.

The same locational information for each planned marking was also transferred to a portable radiology workstation (ZioCube®; ZioSoft Inc., Tokyo, Japan) that had been installed in a laptop computer readily available in the operation room. The lung component was extracted from the DICOM data. Using axial CT images, the tumor component was extracted and pseudo-colored with red. Similarly, a ball-shaped component was extracted at each planned marking location and pseudo-colored with blue. These images were overlaid to compose the final planned three-dimensional images. Details of mapping design using different workstations are also shown in supplementary Fig. 1.

ENB VAL-MAP

The patient was brought into the operation room, general anesthesia was induced, and a single-lumen tracheal tube of > 7.0 was intubated. The patient was kept in the supine position on an appropriately placed location board that emitted low-frequency electromagnetic waves. A locatable guide (LG)-containing sensors that allowed tracking of position and orientation in the magnetic field was inserted in an extended working channel (EWC). The LG/EWC was inserted through the working channel of a therapeutic bronchoscope (BF-1T260; Olympus, Tokyo, Japan). Following the manufacturer's instructions, the registration process was completed and the LG/EWC was advanced toward the target (i.e., each planned marking location) under real-time navigation in the same manner as regular transbronchial biopsy using the system [12]. Once the LG/EWC reached the target in the virtual image (Fig. 2a), the EWC was locked in place, the LG was removed, and then, a metal-tip catheter (PW-6P-1; Olympus) preloaded with 0.7 ml of indigo carmine was inserted into the EWC. And then, a fluoroscope was turned on to observe the location of the catheter tip. Once it was confirmed to have reached the pleura, indigo carmine was injected in the same manner as regular VAL-MAP as previously described. [7]. If the LG/EWC did not reach the target even after making efforts for a certain period of time (maximum of approximately 10 min), injection of indigo carmine was performed at the closest location the LG could reach. If the location was completely off the target, the injection attempt was abandoned.

These processes were repeated for all of the target markings. Real-time navigation of the virtual images was video-recorded in the bronchoscope for later on-site adjustment.

On-site adjustment

The radiology workstation with the established three-dimensional image was brought into the operation room. Once all the markings had been completed, the patient underwent a series of preparations for the following surgery, including replacement of the intratracheal tube to a double-lumen tube, changing of the position from supine to decubitus, and sterilization (Fig. 1). During this time, one surgeon (M.S.) worked on both the ENB machine and the radiology workstation in the corner of the operation room (Fig. 2b).

The recorded video of the real-time navigation was replayed, and the final location of the LG/EWC for each dye marking was observed. If the final location of the LC/EWC reached the planned marking location represented by a green ball on the display of ENB (Fig. 2a), the planned marking in the three-dimensional image of the workstation was left without any change. If the final location of the LG/EWC did not reach the green ball in ENB (Fig. 2c), the locational information obtained from the recorded video images of three different reconstruction planes (axial, coronal, and sagittal views) in ENB (Fig. 2c) was manually transferred to the portable workstation (Fig. 2d) and then replaced with the planned marking. The procedure was repeated for all of the conducted markings to finalize the "adjusted" three-dimensional image (Fig. 2e, f), which was displayed in the operation room to be compared with actual intraoperative view during surgery (Fig. 2g).

Surgery

All surgical procedures were conducted thoracoscopically. Staplers were used to complete wedge resection or segmentectomy. The macroscopic resection margins were measured by the surgeon after resection as previously described [9]. Intraoperative microscopic examination of the resection margins with frozen section was not routinely conducted in this study.

Evaluation

Successful navigation of the LG/EWC to the target (i.e., planned marking displayed as a green ball) was defined as the cross mark overlapping the green ball on the virtual image at the end of navigation (i.e., immediately before removing the LG to insert an injection catheter into the EWC), as shown in Fig. 2a.

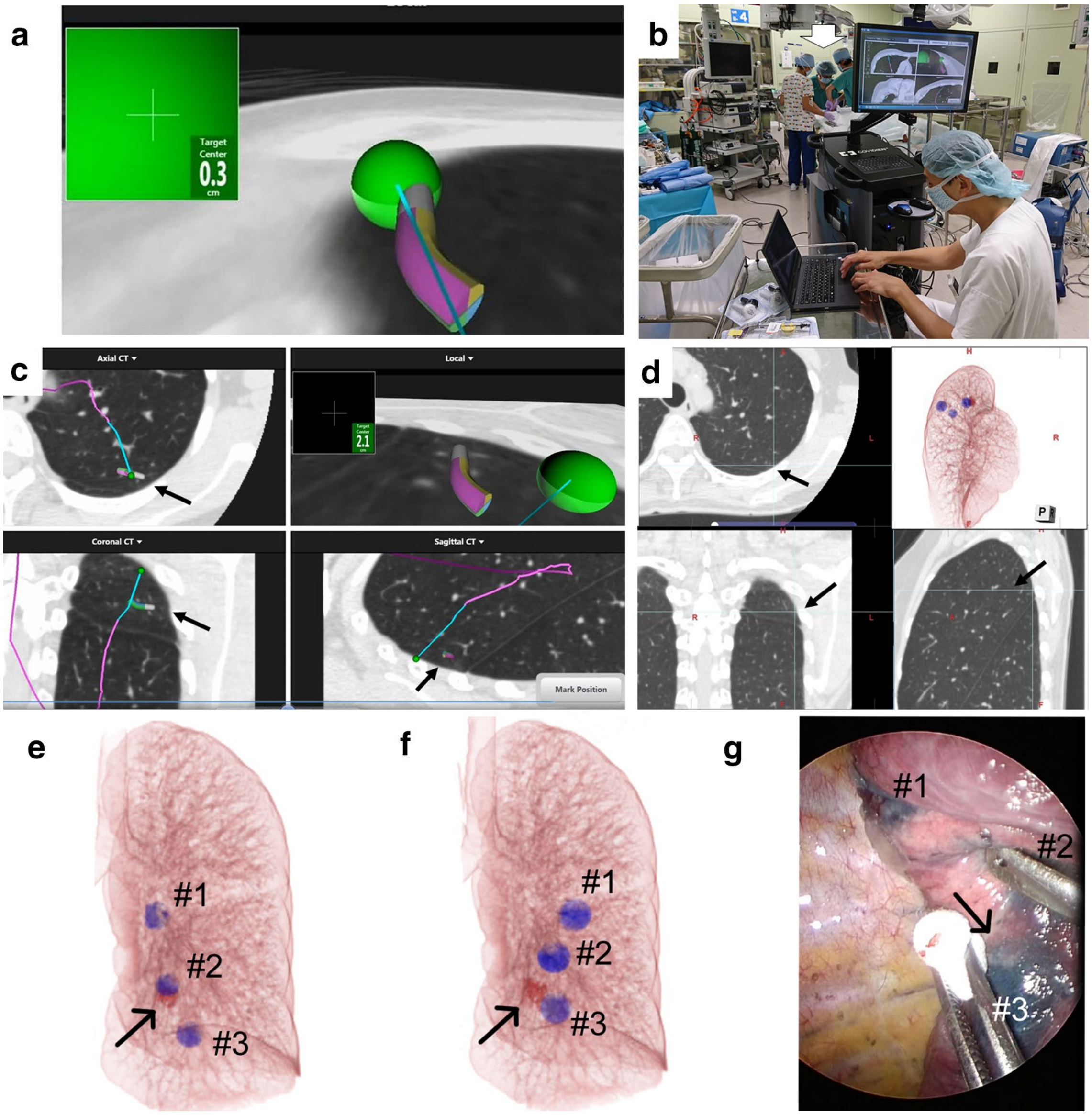

Fig. 2 Technique of on-site adjustment after ENB lung mapping. **a** A virtual ENB images showing that the LG/EWC has reached the target (i.e., planned marking location). For such a successful marking, no adjustment is needed. **b** After ENB lung mapping, the locational information of each dye injection is reviewed and manually transferred to a portable radiology workstation for on-site adjustment. During this time, the patient undergoes preparations for the following surgery, such as tracheal tube exchange by the anesthetists (arrow). **c** When the LG/EWC has not reached the target (i.e., planned marking location; right upper virtual ENB image), the locational information of the dye injection is estimated from the final location of the locatable guide (arrows) displayed in three different planes (axial, coronal, and sagittal). **d** Adjustment of the marking location using the portable radiology workstation. The locational information of the dye injection on ENB is reproduced in the radiology workstation (arrows) to display the marking image at the adjusted location. **e** An example of a mapping plan. The three-dimensional image shows three dye markings (blue spots, #1–#3) and the tumor (red spot with an arrow). **f** A three-dimensional image of the same patient as (**e**) after on-site adjustment. Note the different relationship between the dye markings and the tumor. **g** Actual intraoperative view of the same patient. The tumor was visible on the pleural surface (arrow) located just cranial to the dye mark #3 as indicated by the lung map after on-site adjustment in (**g**). *ENB* electromagnetic navigation bronchoscopy, *LG* locatable guide, *EWC* extended working channel

The location of the actual marking was evaluated intraoperatively, and the accuracy was graded as follows primarily by the surgeon in accordance with other surgeons opinion involved in the procedure: grade 1, the lung map observed during surgery was totally different from what was expected and did not help surgery at all; grade 2, the lung map observed during surgery was mostly different from what was expected but little helped surgery; grade 3, the lung map observed during surgery was partially different from what was expected but was somewhat helpful observed during surgery; grade 4, the lung map observed during surgery was slightly different from what was expected but helpful during surgery; grade 5, the lung map observed during surgery was totally in accord with what was expected and very helpful during surgery.

Data analysis

The initial three patients underwent surgery using only the lung map (no-adjustment group), and the following four patients underwent surgery after on-site adjustment. These two groups were retrospectively compared. The rate of successful navigation of the LG/EWC to the target (i.e., planned marking location) and the accuracy grade were compared between the two groups using the Chi-square test and Mann–Whitney *U* test, respectively.

Results

We began applying ENB to VAL-MAP in October 2017 and made 11 marks for three patients by February 2018 without on-site adjustment (no-adjustment group). We then introduced the method of on-site adjustment using the workstation and made 10 markings for four patients by April 2018 (adjustment group). After establishment of this pilot set of patients, we retrospectively compared the two groups. The demographics of the pilot set of patients are shown in Table 1.

There was no significant difference in the rate of successful navigation of the LG/EWC to the target between the no-adjustment and adjustment groups (36.3% vs. 40.0%, respectively; P = 0.86). Most markings were clearly visible during surgery except for one in the adjustment group, which was excluded from the accuracy grading. The accuracy grade of the anticipated marking location was significantly lower

Table 1 Patient demographics, lesion characteristics, and outcomes

On-site adjustment	Pilot set		Practice set
	No (no-adjustment group)	Yes (adjustment group)	Yes
Number of patients	3	4	17
Age (years)	66.7 ± 10.4	60.8 ± 10.5	64.0 ± 8.4
Male/female	2/1	1/3	9/8
Right/left	2/1	1/3	12/5
Number of lesions	5	4	21
Lesion characteristics			
Pure GGN	1	1	11
Mixed GGN	0	1	2
Solid nodule	3	2	7
Cavity	1	0	1
Diameter (mm)	17.5 ± 10.6	8.8 ± 3.3	8.5 ± 3.9
Depth (mm)	0.5 ± 0.7	5.3 ± 5.0	8.1 ± 5.7
Number of planned markings	13	11	50
Number of actual markings	11	11	50
Time spent on ENB-VAL-MAP	Not recorded	45 ± 23 min	41 ± 14 min
Complications associated with ENB VAL-MAP	None	None	None
Number of visible markings	11	10	48
Number of marks for which LG/EWC reached planned location	4 (36.4)	4 (36.4)	25 (50.0)
Successful resection[a]	4 (80.0)	4 (100)	19 (90.5)
Pathological diagnosis			
Primary lung cancer	2 (40.0)	2 (50.0)	11 (52.4)
Metastatic lung tumor	3 (60.0)	2 (50.0)	6 (28.6)
Benign (inflammation, lymph node)	0 (0.0)	0 (0.0)	4 (19.0)

Data are presented as *n*, *n* (%), or mean ± standard deviation

LG/EWC locatable guide/extended working channel, *GGN* ground glass nodule

[a]Successful resection was defined as a macroscopic resection margin equal to or greater than the tumor diameter or 2 cm at the first resection without a change in the resection plan. The details were previously reported [9]

in the no-adjustment than adjustment group (3.4 ± 1.2 vs. 4.7 ± 0.7, respectively; $P = 0.01$). There was no significant difference in the markings that were placed after successful navigation of the LG/EWC to the target between the no-adjustment and adjustment groups (4.8 ± 0.5 vs. 5.0 ± 0.0, respectively). However, among the markings placed without successful navigation of the LG/EWC to the target, the no-adjustment group had a significantly lower accuracy grade than the adjustment group (2.6 ± 0.5 vs. 4.5 ± 0.8, respectively).

Because these results suggested contribution of on-site adjustment to accurate prediction of the marking locations during surgery, we continued performing on-site adjustment in all subsequent patients (practice set).

In the practice set of patients, 50 markings were conducted to resect 21 lesions in 17 patients. The rate of successful navigation of the LG/EWC to the target was 50.0%, which was somewhat higher than that in the pilot set. Moreover, we divided the 17 patients into the first eight and second nine sets of patients and found that the second set had higher rate of successful navigation than the first (57.1% vs. 40.9%, respectively). The time needed for ENB VAL-MAP (from insertion of the bronchoscope and initial registration to the end of VAL-MAP) was 41 ± 14 min. The time from completion of VAL-MAP to the start of surgery was 43 ± 4.9 min. In all cases, the lung map made by ENB VAL-MAP was compatible with that predicted after on-site adjustment and resection was conducted in a planned manner. The final pathological outcome is shown in Table 1. Nineteen of 21 lesions (90.5%) met the criteria for successful macroscopic resection with adequate resection margins that were either larger than the tumor diameter or 2 cm. The resection margins at the initial stapling for the other two lesions did not meet the criteria: resection margins were 5 mm and 4 mm for pure GGO lesions with diameters of 22 mm and 8 mm, respectively. Additional resection was conducted intraoperatively to secure enough margins for these lesions. The final pathological diagnoses were primary lung cancer ($n = 11$), metastatic pulmonary tumors ($n = 6$), inflammatory lesions ($n = 2$), and intrapulmonary lymph nodes ($n = 2$). None of these lesions were microscopically positive for malignancy at the resection margin after removing the staple line.

Discussion

In the present study, we demonstrated that ENB is applicable to the VAL-MAP technique. Furthermore, the efficacy of predicting the actual "lung map" in the surgical field is significantly enhanced by introduction of on-site adjustment.

One of the most important advantages of ENB VAL-MAP is its logistics. Although the conventional VAL-MAP is a safe, effective, and reproducible procedure [9, 10], multiple steps are necessary before surgery [13]. In particular, a post-mapping CT scan is mandatory to adjust dislocation of markings and achieve accuracy of the lung map [11]. Although the procedure is now covered by public health insurance in Japan, these logistics might hinder distribution of the procedure. In the present study, we have demonstrated that ENB VAL-MAP with use of the on-site adjustment technique can overcome the challenge of logistics by enabling surgeons to complete VAL-MAP in the same general anesthesia session (Fig. 1). The option of using ENB for VAL-MAP may contribute to better dissemination of the VAL-MAP technique.

Importantly, the results of the present study suggest that ENB VAL-MAP is likely to provide lung mapping quality similar to that of conventional VAL-MAP as long as it is used in combination with post-mapping on-site adjustment. In the pilot set, we demonstrated that the use of on-site adjustment significantly enhances the quality of the lung map, especially when real-time navigation fails to reach the planned marking location. Although the probability of reaching the target increased over time through experience, it remained as low as 60% toward the end of the study. However, by applying the on-site adjustment technique, ENB VAL-MAP achieved a lung mapping quality that is satisfactory to surgeons who are familiar with conventional VAL-MAP. Moreover, regarding the outcome of surgery, this technique resulted in successful resection of the tumor with a satisfactory macroscopic resection margin at the first resection in approximately 90% of the cases. This result is comparable with that of a recent multicenter prospective study, which yielded a successful resection rate of 87.8% [9].

It is notable that the successful resection rate was much higher than successful navigation rate (Table 1). This result represents an important feature of VAL-MAP, either conventional or current ENB-assisted technique. First, the multiple marks of VAL-MAP are complementary to each other (i.e., redundancy). Even if one or two marks are missing or totally inaccurate, other reliable marks help surgeons to resect the tumor [7, 8]. Second, even if each mark is inaccurate or different from the original plan, there is a chance to adjust the dislocation by post-mapping CT (conventional VAL-MAP) or by the post-mapping adjustment technique (ENB-VAL-MAP). As the surgeons can tell how the lung map has changed from the original plan, they can conduct surgery referring to the renewed information on the adjusted lung map [7, 8, 11].

Although the present study demonstrated the efficacy of the ENB VAL-MAP technique using on-site adjustment, the process is still complex and needs further sophistication. We began with the "mapping mode" of the workstation, then used the virtual bronchoscope of the ENB system, and finally conducted on-site adjustment using a portable radiology workstation. Indeed, if the first workstation had not been a stand-alone desktop workstation, but, instead, had been available in the operation room, we would not have had to introduce another workstation for on-site adjustment. Conversely, although we used the mapping mode to design the lung map, the designing procedure of VAL-MAP can be replaced by any workstation or virtual bronchoscope, including a portable one [10]. Ideally, the whole process should be integrated into a single ENB system wherein we can design the map, navigate the bronchoscope, and conduct on-site adjustment using the three-dimensional information obtained through navigation.

We also recognized a limitation of ENB VAL-MAP with respect to the operation time used for ENB. On average, we spent 36 min for the lung mapping procedure using ENB; however, after we had gained adequate experience, the whole process of ENB including the three markings could be completed in 19 min. Additional time was required for tracheal tube replacement by the anesthetists. On-site adjustment did not require extra time in the operation room, because it was completed when the tube was replaced during the positional change. In general, we anticipate 1 extra hour of operation time when using ENB VAL-MAP compared with that after conventional VAL-MAP, in which the entire mapping procedure and adjustment are completed at the time of surgery. Thus, compared with conventional VAL-MAP, the major advantage of ENB VAL-MAP is the ability to complete the mapping process in the operation room in a single general anesthesia session, while a disadvantage is extension of the operation time. The use of VAL-MAP reportedly shortens the operation time during wedge resection [14], which might compensate for the extra operation time in ENB VAL-MAP.

We acknowledge that the present study has multiple limitations. First, this was an exploratory study in a single center, wherein the data were retrospectively analyzed. Second, the quality of the lung map made by ENB VAL-MAP with on-site adjustment needs further confirmation. In this study, "accuracy grading" was used to evaluate the accuracy of the estimated marking locations based on intra-operative findings. However, the discrepancy between the planned and actual marking locations was not objectively measured as performed with post-mapping CT in a previous study [11]. Theoretically, ENB VAL-MAP cannot be more accurate than conventional VAL-MAP, in which locations of actual marks are confirmed by post-mapping CT. Thus, for more precise evaluation of the post-mapping on-site adjustment technique, comparison of the locational information between post-mapping CT and post-mapping on-site adjustment, or comparison of accuracy with or without on-site adjustment using post-mapping CT is needed. Third, sublobar lung resection assisted by ENB VAL-MAP resulted in a resection failure rate of 10% (i.e., the macroscopic resection margin was less than the tumor diameter at the first resection). Although the result is not inferior to conventional VAL-MAP, we recently demonstrated the limitations of VAL-MAP using dye markings on the lung surface for resection of deeply located lesions [9]. This is not a problem associated with ENB VAL-MAP but an inherent limitation of the present technique. Thus, to overcome the limitation of two-dimensional lung mapping on the lung surface using dye, we have recently developed a new technique called VAL-MAP 2.0 by combining dye mapping with bronchoscopic placement of a microcoil. This technique enables three-dimensional lung mapping that includes information regarding depth [15]. We are currently performing a multicenter prospective study using the VAL-MAP 2.0 technique. We anticipate that the VAL-MAP 2.0 technique can be well integrated into the ENB VAL-MAP technique that we demonstrated in the present study.

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Compliance with ethical standards

Conflict of interest There is no conflict of interest to declare.

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