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Review Article

Robotic-assisted bronchoscopy in the diagnosis of peripheral pulmonary lesions

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ABSTRACT

More peripheral pulmonary lesions (PPLs) are detected by low-dose helical computed tomography (CT) either incidentally or via dedicated lung cancer screening programs. Thus, using methods for safe and accurate diagnosis of these lesions has become increasingly important. Transthoracic needle aspiration (TTNA) and transbronchial lung biopsy (TBLB) are routinely performed during the diagnostic workup for PPLs. However, TTNA often carries the risk of pneumothorax, uncontrollable airway hemorrhage, and does not allow mediastinal staging in one procedure. In contrast, traditional TBLB often has a poorer diagnostic yield despite fewer complications. With the ongoing development of technology applied to bronchoscopy, guided bronchoscopy has become widely used and the diagnostic yield of TBLB has improved. Additionally, guided bronchoscopy continues to demonstrate a better safety profile than TTNA. In recent years, robotic-assisted bronchoscopy (RAB) has been introduced and implemented in the diagnosis of PPLs. At present, RAB has two platforms that are commercially available: Monarch™ and Ion™; several other platforms are under development. Both systems differ in characteristics, advantages, and limitations and offer features not seen in previous guided bronchoscopy. Several studies, including cadaveric model studies and clinical trials, have been conducted to examine the feasibility and performance of RAB using these two systems; large multicenter studies are underway. In this review, published experimental results, focusing on diagnostic yield and complications of RAB, are analyzed and the potential clinical application of RAB is discussed, which will enable the operators to have a clear overview of RAB.

Introduction

Lung cancer is one of the most commonly diagnosed cancers and is the leading cause of cancer death worldwide.[1] The utilization of low-dose helical computed tomography (CT) for lung cancer screening has increased the detection rate of peripheral pulmonary lesions (PPLs), thereby contributing to the reduction of mortality from lung cancer among high-risk individuals.[2] The differential diagnosis for lung nodules is broad, ranging from benign disease (e.g., infection) to malignancy. Therefore, nodules that require tissue sampling require a timely diagnosis that is both accurate and minimally invasive with a low complication profile.

Image-guided transthoracic needle aspiration (TTNA) is an important modality in the diagnosis of lung diseases. The overall diagnostic accuracy of CT-guided TTNA is 92.1%, with a sensitivity of 92.1%.[3] However, complications such as pooled pneumothorax (20.5%) and hemorrhage (2.8%) after CT-guided TTNA should also be considered. Traditional transbronchial lung biopsy (TBLB) is another important modality for the diagnosis of PPLs, but is limited to larger lesions with airways visible going into the lesion ("bronchus sign") and the ones that were fluoroscopically visible. Due to the low diagnostic yield of traditional TBLB, many developments have been made in bronchoscopy to aid the endoscopist in the guided sampling of the PPLs. These include radial probe endobronchial ultrasound (R-EBUS), ultrathin bronchoscopy (UTB), guide sheath (GS), virtual bronchoscopy (VB), and electromagnetic navigation bronchoscopy (ENB). A meta-analysis covering 41 studies showed that the overall diagnostic accuracy of R-EBUS and ENB was 72.4% and 76.4%, respectively. Additionally, both R-EBUS and ENB had comparative safety profiles of <2% complications.[4] Oki et al[5] reported that the overall diagnostic yield of UTB was approximately 70.1% and

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the complication rate was 2.8%. Other studies also demonstrated lower diagnostic yields for the previous guided bronchoscopy than the diagnostic yield of TTNA, but without the associated high risk of complications seen in TTNA.[6–8] An unmet need has been defined for the diagnosis of PPLs through previous studies: to build a system with high diagnostic yields comparable to TTNA but with the safety record of guided bronchoscopy.

Robotic-assisted surgical platforms have been widely adopted in different fields, including prostate,[9] lung,[10] gastrointestinal tract,[11] spine,[12] and bladder.[13] In recent years, the development of robotics has been to an endoluminal approach, with the first focus to assist a bronchoscopist in diagnosing PPLs. Our article reviews the existing studies of robotic-assisted bronchoscopy (RAB) and will discuss the potential future applications.

RAB system

To date, two RAB systems have been introduced for use in bronchoscopy. The first to be released was the Monarch™ (Auris Health, Redwood City, CA, USA) platform which was approved by the Food and Drug Administration (FDA) in 2018 while the other system, the Ion™ endoluminal system (Intuitive Surgical, Sunnyvale, CA, USA) was approved in 2019.

The Monarch™ platform combines three distinct navigation techniques, which include electromagnetics, optical pattern recognition, and robotic kinematic data, to assist bronchoscopists in accurately predicting their location in the lung. The outer sheath diameter (6 mm) and inner bronchoscope (4.2 mm, with a 2.1 mm working channel) are based on a telescoping design, which renders the outer sheath to be articulated to 130°, allowing the bronchoscope to be advanced further into the periphery.[14] Additionally, after it is extended from the sheath, the inner bronchoscope can be flexed 180° in all directions, further assisting the bronchoscope in reaching peripheral lesions through the thin, curved, and occasionally tortuous airway. The Monarch™ platform is composed of a robotic tower and a handheld controller. The tower consists of two robotic arms that together control the precise movement, extension, and articulation of the bronchoscope. Operators can control the bronchoscope using a familiar controller interface including buttons and two joysticks. The motion direction of the RAB is adjusted according to the virtual navigation and real bronchoscope images displayed on the screen. Once the bronchoscope reaches the target, the Monarch™ can park it in place, reducing unnecessary movement and providing uninterrupted vision. Another unique feature of this system is the always present optics and suction, allowing precise guided movement of the scope in real-time scenarios of instrument placement and sampling. The 2.1-mm inner working channel allows the passage of any off-the-shelf instruments available to a bronchoscopist. A case using Monarch™ sampling was shown in Fig. 1.

The Ion™ endoluminal system consists of an ultrathin, fully articulating catheter with a 3.5-mm outer diameter and 2-mm working channel, allowing a 1.8-mm video probe or a biopsy needle to pass and provide visualization or perform biopsy when operating. This optical probe must be removed during sampling. The catheter includes a fiber-optic shape sensor which provides position and shape information with feedback to a console hundreds of times per second.[14] The Ion™ endoluminal system is composed of a system cart and a motion control console. The flexible instrument manipulator on the cart is used to manipulate the catheter and the monitor shows the images of virtual navigation, fluoroscopy, and direct visualization with the optical probe in the scope. During the bronchoscopy, physicians use a motion control console with a trackball and a scroll wheel to direct the bronchoscope and navigate to the target nodules via a pre-planned pathway. A case using Ion™ sampling is shown in Fig. 2. Sampling can be done using the Flexion Biopsy Needle, available in 19G, 21G, and 23G. The special biopsy needle can extend up to 3 cm and is supported by a retractable sheath during insertion.

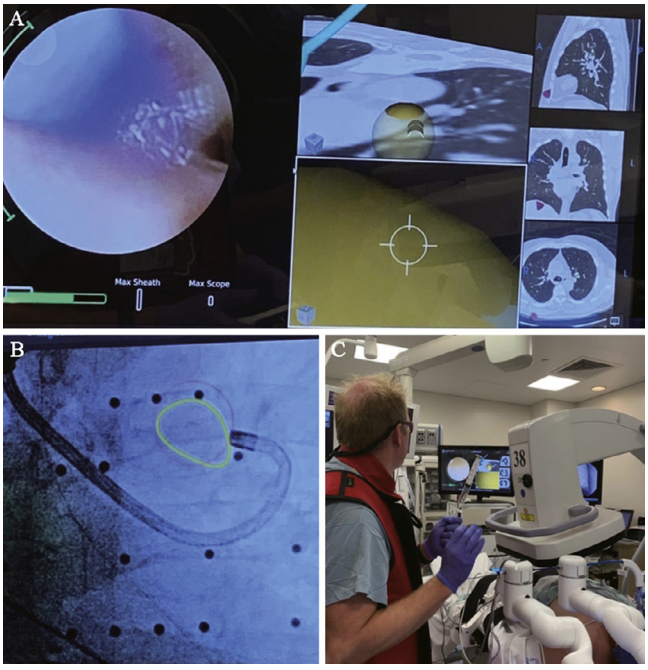

Fig. 1. Monarch sampling in the periphery. (A) The left part of the image is the real-time scope view in the periphery demonstrating the ability to see the needle sheath against the wall with needle penetration. The ability to see your instruments in the periphery is key to ensure sample quality. The screens on the right demonstrate the virtual targeting and the single slice CT view to help confirm location. (B) Fluoroscopic view of the Monarch getting ready to sample. (C) The operator is able to control the robot and the instrumentation while utilizing any additional technologies (X-ray, radial endobronchial ultrasound, etc.). CT: Computed tomography.

The performance of RAB

Many studies have examined the use of RAB in the diagnosis of PPLs [Table 1]. Both systems have been used in several studies and are still being used in several ongoing trials.

Studies using Monarch™ platform

Rojas-Solano et al.[15] first reported the feasibility of the Monarch™ RAB system using first-generation hardware and software. Diagnostic biopsy samples were obtained from 93.3% (14/15) of patients. No serious adverse events, including pneumothorax and significant bleeding, occurred.

The REACH trial by Chen and Gillespie.[16] demonstrated that the Monarch™ robotic endoscopic system was advanced further into all 10 segmental bronchi than a conventional thin bronchoscopy of identical caliber, both by generation count and by insertion depth in human cadaveric lungs. The Monarch™ went further than the P-190 Olympus scope and reached near the pleura. The ACCESS study[17] demonstrated the ability of the Monarch™ robotic bronchoscope to reach and access 67 artificial tumor targets that could produce a realistic ultrasound image of tissue dense lesions visible on CT scanning in 8 cadaver models. The overall diagnostic yield of transbronchial needle aspiration (TBNA) and transbronchial forceps biopsy was 97.0% (65/67). There was no significant difference between the diagnostic yield for nodules measuring 21–30 mm and nodules smaller than 20 mm (100% *vs.* 95.7%, $P > 0.999$). Importantly, regardless of the distance from the pleura or the presence of an eccentric or concentric ultrasound image of the lesion, the RAB system was able to biopsy the lesion successfully. The study was performed in cadaver models lacking any respiratory changes which could not totally reflect the nature of the live human lung. In an-

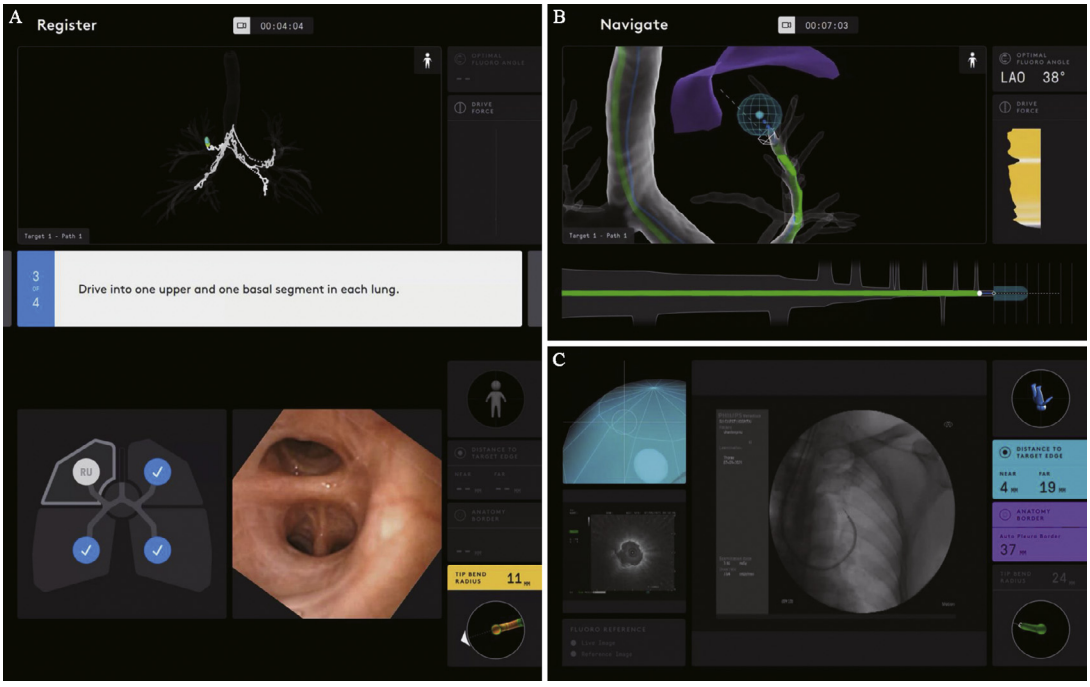

Fig. 2. Ion sampling in the periphery. (A) Screenshot of the registration process. (B) Navigation to the nodule per the pathway (blue curved line) created by the PlanPoint software. The green curved line showed the location of the catheter to the target (blue ball). (C) The radial endobronchial ultrasound image and fluoroscopy image confirming the nodule, distances from the catheter tip to the target and to the visceral pleural border were displayed on the screen.

Table 1
Studies on the diagnosis of pulmonary lesions by RAB.

No.	Study	System	Design	Subject	No. of lesions	Lesion size (mm)	Diagnostic yield (%)	Complication
1	Rojas-Solano et al[15]	Monarch	Prospective	Human	15	26 (range 10–63)	93.3	Three unrelated complications
2	Chen et al[17]	Monarch	Prospective	Cadaver	67	20.4 (range 9.6–28.3)	97.0	None
3	Chen et al[18]	Monarch	Prospective	Human	54	23 (Q_1–Q_3: 15–29)	74.1	Two pneumothorax (3.7%)
4	Chaddha et al[19]	Monarch	Retrospective	Human	167	25.0 ± 15.0 (largest diameter)	69.1–77.0	Six pneumothorax (3.6%), four significant bleeding (2.4%)
5	Ekeke et al[20]	Monarch	Retrospective	Human	25	10–20 (range 8–69)	96.0	None
6	Fielding et al[22]	Ion	Retrospective	Human	29	14.8 ± 4.5 (largest diameter)	79.3	None
7	Yarmus et al[23]	Ion	Prospective	Cadaver	20	16.5 ± 1.5	80.0	Not mentioned
8	Bajwa et al[24]	Ion	Retrospective	Human	76	17 (range 6–70)	92.0	None
9	Benn et al[25]	Ion	Prospective	Human	59	21.9 ± 11.9 (largest diameter)	86.0	Two pneumothorax (3.8%)
10	Kalchiem-Dekel et al[26]	Ion	Prospective	Human	159	18 (Q_1–Q_3: 13–27)	81.7	Four complications (3.0%) with two pneumothorax
11	Folch et al[28]	Ion	Prospective	Human	74	18.42 ± 5.44 (axial) 16.75 ± 5.78 (coronal) 17.36 ± 6.20 (sagittal)	Not available	None
12	Reisenauer et al[29]	Ion	Prospective	Human	270	18.84 ± 6.50 (largest diameter)	Not available	Eight pneumothorax (3.3%), two airway bleeding (0.8%)
13	Simoff et al[30]	Ion	Prospective	Human	67	17.5 (axial, range 12.0–24.0) 16.0 (coronal, 11.8–21.0) 16.2 (sagittal, 12.0–22.0)	Not available	Two unrelated complications

RAB: Robotic-assisted bronchoscopy.

other study, Chen et al[18] reported a prospective multicenter pilot study of RAB utilizing the first-generation planning and navigation software. The BENEFIT study enrolled 55 human subjects across five study sites. The lesion was successfully localized in 96.2% (51/53) of subjects and the observed adverse event rate was low (3.7%). The overall diagnostic yield was 74.1% and was not affected by a concentric EBUS view, absent bronchus sign, or different lesion sizes.

A retrospective study conducted by Chaddha et al[19] including 167 lesions in 165 patients showed that the diagnostic yield of RAB ranged from 69.1% to 77.0% assuming all the biopsy samples proven as inflammation without follow-up were non-diagnostic. This study also utilized the first generation of navigation software and pre-release versions of planning software. The average size of the largest measurable diameter of the lesions was 25.0 ± 15.0 mm and 70.7% of the lesions were located in the peripheral third of the lung. A total of 10 (6.0%) cases suffered from adverse events, including 6 pneumothoraxes and 4 incidents of significant bleeding. Furthermore, this study showed that diagnostic yield did not depend on the location, centrality, and lesion size.

Ekeke et al[20] described a pilot study of lung nodule evaluation using RAB in 25 male patients. Adequate sampling was obtained from 96% (24/25) of the patients with an actionable diagnosis. No patient suffered from post-procedure morbidity. The large-scale TARGET study is still underway. Lead by Septimiu Murgu, this large cohort study (NCT04182815) is enrolling 1200 participants at up to 30 investigative sites. The study evaluates robotic-assisted TBLB using the Monarch™ platform and is expected to be completed in January 2023.[21]

Studies using Ion™ endoluminal system

Fielding et al[22] tested the RAB in a retrospective study enrolling 29 subjects and demonstrated the overall diagnostic yield of 79.3% with a diagnostic yield of 88.2% for malignant lesions. No severe pneumothorax, bleeding, or airway injury occurred.

Yarmus et al[23] performed a prospective, randomized comparative study in five human cadaveric torsos covering 60 procedures on 20 peripheral pulmonary nodules to compare the ability of three guided bronchoscopy approaches including ENB, UTB with R-EBUS, and RAB for diagnosing peripheral pulmonary nodules. Although there was no significant difference between UTB with R-EBUS and ENB (25% *vs*. 45%, $P = 0.19$), RAB achieved a higher rate of successful localization and puncture than ENB (80% *vs*. 45%, $P = 0.022$). However, the ENB system used was not calibrated or mapped for the room. Among unsuccessful localization, the median distance from needle to target also showed a significant difference comparing UTB with R-EBUS, ENB, and RAB ($P = 0.0014$).

Bajwa et al[24] reported the diagnostic yield of 76 consecutive cases of RAB at a single center was 92% regardless of acquisition or type of an R-EBUS signal. There were no complications. Benn et al[25] tested the sensitivity for malignancy and overall diagnostic accuracy for RAB combined with cone beam CT (CBCT) for secondary confirmation. The study enrolled 52 consecutive patients including 59 nodules regardless of age, previous malignancy history, or thoracic surgery history. After navigation was completed, a biopsy needle was inserted into the target lesion. CBCT was performed to confirm needle position and proper adjustments were made if it was necessary before biopsy. The overall diagnostic yield was 86% (51/59) with an 84% (31/37) procedural sensitivity for malignancy. Only two patients developed pneumothorax postoperatively; one of them required tube thoracostomy. No bleeding was reported.

Kalchiem-Dekel et al[26] tested the value of shape-sensing RAB, by targeting 159 nodules from 131 consecutive RAB procedures. The overall diagnostic yield was 81.7% (130/159). The diagnostic yield was 66.7%, 70.4%, 92.9%, and 100.0% for lesions ≤1.00 cm, 1.01–2.00 cm, 2.01–3.00 cm, and >3.00 cm, respectively. Unlike other previous studies, univariate analysis showed that lesion size and lung centrality were significantly associated with diagnostic yield, but not the bronchus sign status and the R-EBUS view. Four RAB-related adverse events occurred and two required percutaneous drainage while no relevant severe bleeding, airway perforation, or deaths took place.

One prospective multicenter study (NCT03893539) plans to enroll 360 people to evaluate the clinical utility and performance of the Ion™ endoluminal system in approaching and facilitating pulmonary tissue sampling of pulmonary nodules. This study is expected to be completed in January 2023.[27] Folch et al[28] reported that navigation of the catheter within 2 cm of the planned target location and biopsy completion was achieved in 69 (98%) cases in the underway multicenter study including 74 nodules in 70 subjects with no complications. These early results are encouraging and we are expecting the final diagnostic yield and sensitivity of the study. In an ongoing multicenter trial by Reisenaur et al[29] covering 241 patients with 270 peripheral pulmonary nodules, the feasibility and safety of the study were described, in which eight patients (3.3%) suffered from asymptomatic pneumothorax and one required pigtail catheter placement. Two subjects (0.8%) experienced airway bleeding which resolved after 5-min tamponade. Simoff et al[30] also reported the lead-in stage of the study, providing investigators and staff with their human experience with the Ion™ system. Sixty patients with 67 nodules were targeted for biopsy. Median largest cardinal diameter was 20.0 mm. Biopsy completion was 97.0%. No pneumothorax or airway bleeding of any grade was reported.

Discussion

Diagnostic yield

The meta-analysis reported the diagnostic yield of CT-guided TTNA was 92.1%.[3] The prospective, multicenter NAVIGATE study, which included >1000 subjects, reported a diagnostic yield of 73% for ENB in diagnosing PPL after one year of follow-up.[31] The diagnostic yield of RAB in diagnosing PPL ranged from 69.1% to 96.0% reported by the existing clinical trials of RAB. Compared with traditional bronchoscopy, RAB appears to offer obvious advantages. However, more clinical studies are needed to provide data on its performance compared to CT-guided TTNA and other guided bronchoscopy. Although Yarmus et al[23] reported a randomized trial in which RAB outperformed ENB in diagnosis, this study was conducted in cadaver models with other limitations listed previously. Despite current trials which have shown positive diagnostic results of RAB, multicenter trials with larger numbers of subjects are needed to provide further support. As with any new technology, the lack of RAB-related experience may also be considered as a factor affecting the diagnostic yield across studies, as well as generational changes in the software that drive these machines.

The factors influencing the diagnostic yield of RAB are not consistent across studies. Chaddha et al[19] reported that RAB resulted in a higher diagnostic yield for lesions with a bronchus sign, and that diagnostic yield was independent of lesion size. Kalchiem-Dekel et al[26] reported that according to the univariate analysis of the study, lesion size and lung centrality correlated significantly with diagnostic yield. However, Bajwa et al[24] and Chen et al[18] reported that the type of R-EBUS signal was not associated with diagnostic yield. Clarifying the factors affecting the diagnostic yield can further assist the bronchoscopist in improving the accuracy of the diagnosis process. However, the existing data are not enough to enable us to obtain a consistent result, and we still need to pay attention to this point in future studies.

Complications

The incidence of pneumothorax in CT-guided TTNA was as high as 25.9%,[32] whereas a meta-analysis showed that the incidence of pneumothorax in guided bronchoscopy, including VB, ENB, R-EBUS, GS, or UTB, was only 1.5%.[8] In the RAB studies, some trials reported no post-procedure complications, while the incidence of pneumothorax reported in some studies ranged from 1.5% to 3.8%, with even lower rates of

airway bleeding, ranging from 0.8% to 2.4%, which was not much different from other guided bronchoscopy.[15,17–20,22–26,28–30] Although it is still not clear whether RAB has an advantage over CT-guided TTNA in diagnostic certainty, the incidence of complications in RAB is significantly lower than that in CT-guided TTNA. Robotic manipulation of the bronchoscope deprives physicians of tactile feedback. Severe airway bleeding still exists,[19,29] albeit infrequently, so airway injury, not just pneumothorax, should be considered as a complication endpoint in future studies. Further consideration should be given to the possible need for emergency management of severe airway injury and bleeding caused by RAB.

Advantages and limitations

The diagnostic yield of the Monarch™ platform ranged from 69.1% to 96.0%,[15,17–20] while that of the Ion™ endoluminal system ranged from 79.3% to 92.0%.[22–26] Advantages, costs, and limitations of the systems should be considered before incorporating these devices into endoscopy work. The RAB platform ensures that the bronchoscope stays in place and prevents movement during tissue biopsy. The articulation in all directions and ability to generate force to overcome airway resistance helps the bronchoscope reach deeper into the convoluted bronchus.[14] Additionally, the Monarch™ platform maintains continuous visualization while moving toward the target, while the fiber-optic shape sensor of the Ion™ endoluminal system provides continuous position and shape feedback during intervention.

There are some limitations about RAB. A clear vision was difficult to achieve given the small diameter of the distal bronchus. Murgu[33] previously reported on his experience with the Monarch™ platform, which mentioned optimizing bronchoscopic visualization in the distal airways by allowing pressure balance between the atmosphere and the target airway by means of disconnecting the proximal valve temporarily or insufflating 30–60 mL of air. In addition, using RAB, there will be no tactile feedback during the advancement of the endoscope. Thus, in theory, it might cause airway injury, pneumothorax, or bleeding. The preventive strategies should be considered.

The Monarch™ platform is not recommended for patients with implanted cardiac electronic devices because of its reliance on electromagnetic navigation technology.[34] However, a study attempting to perform the bronchoscopy without electromagnetic navigation has been conducted and this seems feasible.[33] As RAB suffers from limited suction, which is worse in the Ion™, it is therefore necessary to use conventional bronchoscopy to clean up the secretions before performing RAB.

Although RAB navigation can guide the correct path, failure of the bronchoscope to reach the target location or failure of biopsy needle sampling will still lead to false negatives. This makes real-time tool-in-lesion confirmation a challenge with RAB. For this reason, RAB still needs and benefits from R-EBUS, CBCT, and other complementary technologies for PPL localization.[35] Future robotic platforms offer direct integration of information from localization technologies into their navigation.

The price of a robotic system has also been a concern. New technology may come with higher cost. However, long-term use of the facilities, early and effective treatment after accurate diagnosis, and avoidance of unnecessary medical costs resulting from complications should also be considered. In these circumstances, the expenditure on the equipment and the system may be acceptable.

Promising application of RAB

Several recent case reports and studies on bronchoscopic treatment included radiofrequency ablation (RFA),[36] microwave ablation (MWA),[37] and photodynamic ablation (PDT).[38] Bronchoscopic therapeutics for PPLs offer a promising benefit with possibly fewer complications than other therapies such as surgery, stereotactic body radiation therapy (SBRT), and percutaneous ablative techniques.[39] Given the stability and high precision of RAB when used in the bronchus, these platforms are expected to aid physicians in performing bronchoscopic treatment of peripheral pulmonary nodules. With RAB, interventional procedures can be manipulated with greater support and accuracy, and physicians' hands can be freed for other necessary procedures during the treatment time.

Another superior benefit of RAB is its remote manipulation capability. This function has more practical implications for the respiratory system than any other system. Many respiratory diseases spread in the form of aerosols, and the interventions such as bronchoscopic procedures of ill patients can generate aerosols, thus exaggerating the spread of infectious diseases.[40] The RAB protects the operators from exposure to susceptible environments during routine bronchoscopy and treatment. The potential advancements of RAB can also allow for the bronchoscopic diagnosis and treatment of patients infected with the coronavirus disease 2019 (COVID-19).[41]

Conclusions

Based on the existing clinical trial results with two systems, RAB has some advantages in effective diagnosis and reduction of complications, with a potential prospect in clinical applications of interventional therapy and prevention of disease transmission from patients to operators. More data, continued innovation by the manufacturers, and competition from other devices entering the RAB space make robotics promising for the future of bronchoscopy.

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Conflicts of interest

None.

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